Endovascular aneurysm repair

Results and exploration of new frontiers

E.L.G. VERHOEVEN

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Stellingen behorende bij het proefschrift

■ ENDOVASCULAR ANEURYSM REPAIR
Results and exploration of new frontiers

1 Endovasculaire behandeling van het aneurysma van de aorta abdominalis is te verkiezen boven open behandeling. *(dit proefschrift)*

2 De meeste complicaties van een endovasculaire behandeling van het aneurysma van de aorta abdominalis kunnen endovasculair behandeld worden. *(dit proefschrift)*

3 Hypotensie accepteren is de eerste stap in de successvolle behandeling van het geruptureerd aneurysma van de aorta abdominalis. *(dit proefschrift)*

4 Locale anesthesie heeft de voorkeur bij de endovasculaire behandeling van het aneurysma van de aorta abdominalis. *(dit proefschrift)*

5 Protheses met fenestraties en zijtakken maken het mogelijk juxta- en suprarenale aneurysmata endovasculair te behandelen. *(dit proefschrift)*

6 In de 21^{stc} eeuw hoort een centrumziekenhuis een operatiekamer te hebben met dezelfde faciliteiten voor angiografie als de afdeling Radiologie. *(dit proefschrift)*

7 Een nieuwe techniek heeft tijd nodig om te groeien.

8 De *chirurgen van de 20ste eeuw* zullen over honderd jaar waarschijnlijk bestempeld worden als de *slagers van de 20ste eeuw.*

9 Concerns for man and his fate must always form the chief interest of all technical endeavors. Never forget this in the midst of your diagrams and equations. *(Albert Einstein)*

10 Dat er intelligente buitenaardse wezens bestaan wordt feilloos bewezen door het feit dat ze nog geen contact met ons hebben opgenomen. *(Loesje)*

11 De *acute vaatchirurgie* dient acuut gecentraliseerd te worden.

12 Een endovasculair centrum kan niet zonder regionale samenwerking.

13 There is no point in living if you can't feel alive. *(Sophie Marceau alias Electra in James Bond "The world is not enough")*

Rijks*universiteit* Groningen

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Proefschrift

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Voor Margo en Daniël,

Contents

Chapter I

■ DESIGN AND RATIONALE OF THE THESIS

Over the last decades, surgeons of all specialties have tried to minimize the impact of surgery on their patients. This resulted in the introduction and further development of many minimally invasive techniques. In orthopedic surgery, this evolution has been embodied by the successful introduction of arthroscopy techniques. In abdominal surgery and gynecology, laparoscopy now plays an important role in the diagnosis and treatment of a variety of diseases. In interventional cardiology, percutaneous transluminal angioplasty and stenting of lesions in the coronary arteries have emerged as a less invasive alternative for myocardial revascularization.

In vascular surgery, in concert with the evolution in cardiology, percutaneous angioplasty and stenting of stenosed vessels and even short segment occlusions, can often replace open procedures such as endarterectomy and bypass surgery. This resulted in a multi-disciplinary approach in decision making, and an increased co-operation between vascular surgeons and interventional radiologists. For a long time, however, the treatment of aneurysms remained reserved to open surgical techniques. It is only about a decade and a half ago that attempts were started to treat aneurysms with minimally invasive procedures. These attempts were first made with aneurysms of the abdominal aorta, and later with aneurysms of the thoracic aorta as well. Thanks to these developments, new options for the treatment of high-risk vascular patients were created. Many patients who were regarded inoperable with open techniques could now be offered an alternative with less risk, thereby avoiding a laparotomy or thoracotomy, and clamping of the aorta. Co-operation between vascular surgery, interventional radiology, and medical industry resulted in a rapid evolution from home-made stent-grafts to sophisticated commercially available devices.

Endovascular repair of aortic aneurysms (EVAR) was first welcomed with great enthusiasm. It was obvious that such a minimal invasive approach would present with advantages. This enthusiasm diminished when non-expected early and late complications arose, and some critics were quick to change their mind from unconditional enthusiasm to full condemnation of the technique. An editorial in the British Journal of Surgery even qualified EVAR as a "failed experiment" (Br J Surg 2001;88:1281-1282). Both early over-enthusiastic reactions and quick condemnations demonstrate that new surgical techniques need thorough evaluation before they deserve a place in common surgical practice.

This thesis studies the possible advantages of EVAR, but also reports the complications of the technique. Furthermore, this thesis explores new applications and future developments of the technique.

First, we have concentrated on the comparison of EVAR with open repair. To this purpose, the multicenter Dutch Randomized Endovascular Aneurysm Management (DREAM) –trial was carried out. The trial compares EVAR with open treatment in 345 patients with an abdominal aortic aneurysm. Chapter II describes the results of this study.

Next, we have concentrated on the question whether we could further reduce the operative risk of EVAR by applying local anesthesia rather than epidural or general anesthesia. Chapter III reports the results of a prospective continuous cohort of patients treated by EVAR with a unified anesthetic strategy using local anesthesia as

first choice. Regional and general anesthesia were reserved for patients with predefined individual- or surgical-specific indications only.
We subsequently focused on the complications after EVAR. Chapter IV reports the late complications of EVAR in a consecutive cohort of 308 patients. These complications resulted in a number of re-interventions. Nevertheless, many of these re-interventions could be performed by endovascular means again. The frequency, type, and outcome of these re-interventions are reported.
The main reason to treat abdominal aortic aneurysms is to prevent a life-threatening rupture. The open treatment of ruptured aneurysms still carries a high mortality rate; this mortality was not reduced over the past decades. With the results as reported in the previous chapters, we asked ourselves whether ruptured aneurysms could be treated by endovascular means under local anesthesia. Chapter V reports the results of a feasibility study in 16 patients with an acute abdominal aneurysm, who were treated by endovascular means under local anesthesia as a first choice. Chapter VI reports the results of a larger consecutive cohort of patients with an acute aneurysm, treated by EVAR, in comparison with an historical control group. In addition, the application rate of EVAR in patients with acute aneurysms is reported.
Our subsequent question was directed towards those high-risk patients who were regarded unsuitable for EVAR due to an overly short proximal neck below the renal arteries. To solve this problem, we have tested specially designed stent-grafts with custom-made fenestrations and scallops to incorporate the renal arteries and visceral vessels. These stent-grafts enable a stable proximal fixation while maintaining the patency of the visceral branches. Chapter VII reports our initial results in 18 patients treated by fenestrated EVAR.
Finally, we have extended our interest to applying endovascular techniques in thoraco-abdominal aneurysms. Chapter VIII reviews all ongoing evolutions to treat thoraco-abdominal aneurysms by endovascular means with fenestrated and/or branched grafts, and gives a view of future perspectives. New tools discussed are the use of covered stents inside fenestrated grafts, fully branched devices with the use of bridging stent-grafts, new specially designed flexible sheaths, the use of indwelling wires, and new types of side-branches.
Summaries of the results of our studies, both in English and in Dutch, are given in chapters IX and X, respectively.

Chapter II

A RANDOMISED TRIAL COMPARING CONVENTIONAL AND ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR

Monique Prinssen, M.D.[1], Eric L.G. Verhoeven, M.D.[2], Jaap Buth, M.D.[3], Philippe W.M. Cuypers, M.D.[3], Marc R.H.M. van Sambeek, M.D.[4], Ron Balm, M.D.[5], Erik Buskens, M.D.[6], Diederick E. Grobbee, M.D.[6] and Jan D. Blankensteijn, M.D.[1,7] for the DREAM trial participants*

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The members of the DREAM trial group are listed in the Appendix.

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INTRODUCTION

Elective surgical repair is indicated in patients with a large abdominal aortic aneurysm. The threshold for surgery is still a subject of debate but varies between 5.0 and 5.5 cm in diameter.[1-4] Endovascular repair, pioneered by Parodi and Volodos in the early 1990s, is a less invasive alternative to conventional open repair.[5,6] Endovascular repair usually involves two small incisions made in the groin to expose the femoral arteries. With the use of guidewires, catheters, and specially designed introducer systems, a so-called endograft is assembled inside the abdominal aortic aneurysm under fluoroscopic guidance, thus excluding the aneurysm sac without opening the abdomen.

From its inception, endovascular repair has been used in patients for whom open repair poses a high risk. At the same time, patients with relatively few coexisting conditions are more likely to meet the anatomical criteria for endovascular repair, including the presence of a suitable infrarenal aortic neck and absence of severe aortoiliac tortuosity and calcification in the arterial wall.[7] These factors lead to selection in retrospective analyses and uncontrolled prospective evaluations and make an unbiased assessment of the benefits and risks of the two techniques problematic.[8-15]

Although the initial results of endovascular repair were promising and the less invasive nature of the procedure is appealing to many patients and physicians, evidence is needed that demonstrates the superiority of this approach over open repair, as are conclusive data on cost-effectiveness.[16-18]

We conducted a multicenter, randomised trial — the Dutch Randomised Endovascular Aneurysm Management (DREAM) trial — to compare operative mortality and complications and other outcome events after elective open repair and endovascular repair.

METHODS

- ***Study design and patients***

The design and methods of the trial have been described in detail elsewhere.[19] In brief, patients referred to surgery clinics at 24 centers in the Netherlands and 4 centers in Belgium who had received a diagnosis of an abdominal aortic aneurysm of at least 5 cm in diameter and who were considered suitable candidates for both techniques were randomly assigned to undergo open or endovascular repair, after giving written informed consent. A patient's suitability for endovascular repair was primarily determined by means of endograft-dependent anatomical criteria. A patient's suitability for open repair was determined by an internist or cardiologist. Patients who needed to undergo emergency aneurysm repair were excluded from the study, as were patients with inflammatory aneurysms, anatomical variations, connective-tissue disease, a history of organ transplantations, or a life expectancy of less than two years. The study was performed according to the principles of the Declaration of Helsinki, and the institutional review board of each participating

hospital approved the protocol. Randomisation was carried out centrally by means of a computer-generated permuted-block sequence and stratified according to study center in blocks of four patients.

An independent data-monitoring and ethics committee decided whether to continue the trial on the basis of a single interim analysis of the 30-day end points performed after half the required number of patients had been enrolled. In addition, sequential monitoring was used to monitor the incidence of death from all causes and all moderate and severe complications (not just those at 30 days) in order to safeguard against divergent outcomes beyond the perioperative period, for instance, as a result of endograft failure.[20]

- ***Surgical techniques***

  All repairs were carried out by surgical teams that had performed at least five endovascular procedures. Surgical teams that had performed less than 20 procedures were required to have an experienced proctor assist them during the procedure. Only endovascular devices that had been approved by the U.S. Food and Drug Administration (FDA) or that had an Investigational Device Exemption or Conformité Européen mark were allowed in the study. Endovascular repair typically involves small incisions in the groin to expose both femoral arteries, although some surgeons prefer a total percutaneous approach. The endograft is composed of fabric and metal stents and comes loaded in a specially designed delivery system. Under fluoroscopic guidance, this introducer system is fed through the iliac arteries by means of catheters and guidewires until the endograft is positioned correctly at the top and bottom of the aneurysmal segment of the aorta. Removal of the introducer system allows barbs or other fixing devices to attach to the aortic wall and hold the graft firmly in place, excluding blood flow from the aneurysm sac and removing pressure from the aneurysmal wall. The exposure and aneurysm-repair technique used for open repair was at the surgeon's discretion.

- ***Endpoints***

  Complications were classified and graded according to the reporting standards of the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/International Society for Cardiovascular Surgery.[21,22] Three classes of complications (systemic, local–nonvascular, and local-vascular or implant-related) and three grades of severity (mild, moderate, and severe) were used. Mild complications were not considered in this analysis.

  An outcome adjudication committee, consisting of five vascular surgeons, assessed the class and severity of each complication in a blinded fashion and independently from each other. Disagreements were resolved in a plenary consensus meeting. The primary end point was a composite of operative mortality and moderate or severe complications. Operative complications were defined as those that occurred within 30 days after surgery or more than 30 days after surgery but during the same admission (in-hospital mortality and complications). Other outcome events analyzed were operative mortality and the combination of operative mortality and severe complications.

- ***Statistical analysis***

  The trial was designed to have 80 percent power to show a reduction of 50 percent in the primary end point at the two-sided 5 percent level with endovascular repair, as compared with open repair. The incidence of the primary end point in the open-repair group was expected to be 20 percent. Four hundred patients were required. All analyses were based on all randomised patients who underwent aneurysm repair. Patients were classified according to the original randomised allocation in all analyses. The risk of a complication after open repair was compared with that after endovascular repair, and the results are presented as risk ratios and exact 95 percent confidence intervals, derived with the use of StatXact software (version 6.1, Cytel Software). Means (±SD) together with medians and interquartile ranges were used to describe continuous variables. Frequencies and exact 95 percent confidence intervals were calculated for categorical variables. Differences between treatment groups were evaluated with the use of the Mann–Whitney U test for continuous variables or Fisher's exact test for proportions. All reported P values are two-sided and are not adjusted for multiple testing.

  The study protocol specified that recruitment would end by September 2003, with the enrollment of 400 patients, and that the study would be completed in January 2004. After negotiations with the sponsor of the study (the Health Insurance Council of the Netherlands) about a possible extension, three extra months were allowed, resulting in an eventual enrollment that was 12 percent lower than expected.

  The corresponding author had full responsibility for the conduct of the trial, had full access to all the data, and controlled the decision to publish. The sponsor of the study had no role in the study design.

■ RESULTS

- ***Characteristics of the patients and treatment assignments***

  Between November 2000 and December 2003, 351 patients were randomly assigned to undergo either open repair or endovascular repair (Figure 1). Six patients did not undergo aneurysm repair after randomisation: four declined treatment (three assigned to open repair and one to endovascular repair), one died from a ruptured abdominal aortic aneurysm before undergoing open repair, and one died from pneumonia before undergoing endovascular repair. The remaining 345 patients composed the treatment groups: 174 patients in the open-repair group and 171 in the endovascular-repair group.

  The baseline characteristics of the patients and aneurysms are shown in Table 1.[23] Demographic characteristics, coexisting conditions, cardiovascular risk profiles, the distribution of American Society of Anesthesiologists classifications, and the characteristics of the aneurysm were similar in the two groups.

  There were six crossovers: five patients who were randomly assigned to undergo open repair underwent endovascular repair, and one patient assigned to endovascular repair underwent open repair. Overall, in 96.6 percent of patients (339 of 351), the operation was started according to the randomised assignment.

The median interval between randomisation and surgery was 39 days in both the open-repair group (range, 4 to 260) and the endovascular-repair group (range, 1 to 183; P=0.76).

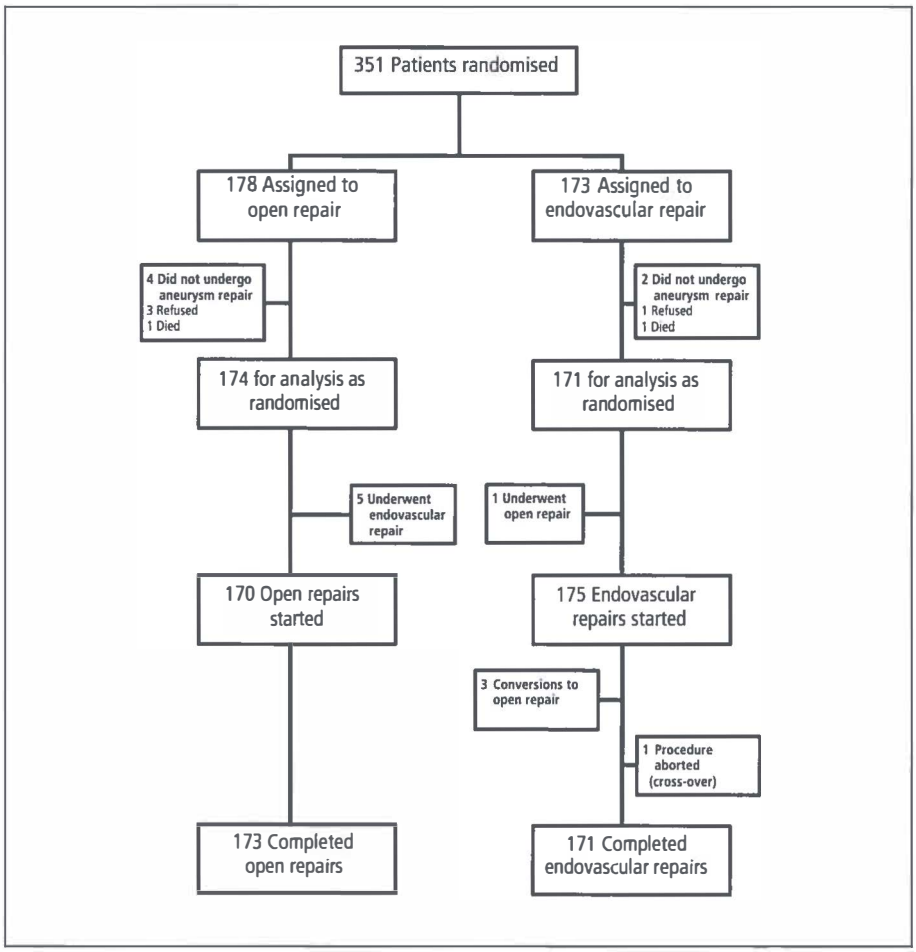

Figure 1. Randomisation, treatment, and analysis of outcome

- ***Surgical and Postoperative Data***

  Characteristics of the aneurysm-repair procedures are shown in Table 2. In three patients who were randomly assigned to undergo endovascular repair, the procedure was converted intraoperatively to an open procedure owing to access problems in two and failed deployment in one. In one patient, who was randomly assigned to open repair and who had crossed over to endovascular repair, the procedure was aborted owing to access problems. The aneurysm was left untreated (Figure 1).

  General anesthesia was used in 98.3 percent of patients in the open-repair group (in all except three of the five patients who crossed over to endovascular repair) and in

*Table 1. Baseline Characteristics of the Patients and Aneurysms, According to Treatment Group.**

Characteristic	Open Repair (N=174)	Endovascular Repair (N=171)	p-value
Age – yr	69.5±6.8	70.7±6.6	0.11
Male sex – no. (%)	157 (90)	159 (93)	0.44
SVS/ISCVS-risk factor score (% moderate or severe)†			
Diabetes Mellitus	9.8	9.9	0.97
Tobacco Use	54.0	64.9	0.07
Hypertension	54.0	57.9	0.92
Hyperlipidemia	53.6	47.0	0.22
Carotid Disease	15.1	13.5	0.71
Cardiac Disease	46.6	40.9	0.30
Renal Disease	7.5	7.6	0.98
Pulmonary Disease	17.8	27.5	0.04
Sum of SVS/ISCVS risk factor scores	4.4±2.5	4.4±2.5	0.70
FEV_1 – (L/sec) ‡	2.6±0.7	2.5±0.7	0.24
Body Mass Index	26.6±4.1	26.2±3.4	0.42
ASA class – no. (%) §			
I healthy status	44 (25)	37 (22)	0.45
II mild systemic disease	106 (61)	119 (70)	0.09
III sever systemic disease	24 (14)	14 (8)	0.12
Previous abdominal surgery – no. (%)	65 (32)	43 (25)	0.15
Maximum diameter – mm (Mean±SD)	60.0±8.5	60.6±9.0	0.68
Median (Interquartile Range)	58 (54-65)	58 (55-65)	
Aneurysm morphology class (Eurostar) – no. (%) ¥			
A: confined to aorta, distal aortic neck available	20 (12)	12 (7)	0.15
B: involves aortic bifurcation, normal iliac arteries	101 (58)	114 (67)	0.12
C: involves both proximal common iliac arteries	20 (12)	16 (9)	0.30
D: extends into one iliac bifurcation	15 (9)	14 (8)	0.90
E: extends into both iliac bifurcations	18 (10)	15 (9)	0.62
Cylindrical shape of infrarenal aortic neck – no. (%)	127 (73)	107 (63)	0.05
Unfavorable features of infrarenal aortic neck – no. (%) ††	74 (43)	92 (54)	0.05
Iliac calcification <25% of the iliac segment – no. (%)	125 (74)	118 (69)	0.40
Unfavorable features of iliac arteries – no. (%) ‡‡	51 (30)	53 (31)	0.81

* Plus-minus values are means±SD.
† Society for Vascular Surgery / International Society for Cardiovascular Surgery risk factor score (0=none; 1=mild; 2=moderate; 3=severe).[21]
‡ FEV1 denotes Forced Expiratory Volume in 1 sec (L/sec).
§ American Society of Anesthesiologists (ASA).
¥ Eurostar classification of aneurysm morphology.[23]
†† Unfavorable neck features: reverse tapered; diameter>28mm; angulated>30°; length<15mm; mural thrombus>2mm; irregular wall or bulge.
‡‡ Unfavorable iliac features: angulation>90°; diameter>18mm; diameter <6mm or >50% stenosis.

54.9 percent of patients in the endovascular-repair group (P<0.001). An aortoaortic (tube) graft was used in 59.8 percent of open repairs and in 1.8 percent of endovascular repairs (P<0.001). At least one internal iliac artery was sacrificed (intentionally or unintentionally) in 4.0 percent of patients in the open-repair

Table 2. Characteristics of the Aneurysm Repair Procedures, According to Treatment Group.

Characteristic	Open Repair (N=174)	Endovascular Repair (N=171)
Type of anesthesia – no. (%)		
General	120 (69)	89 (52)
General and regional	51 (29)	5 (3)
Regional	2 (1) ©	68 (40)
Local	1 (1) ©	9 (5)
Configuration at completion – no. (%)		
conventional tube graft	104 (60)	2 (1) †
conventional bifurcated graft	65 (37)	2 (1) ‡
endovascular tube graft	-	1 (1)
endovascular monoiliac graft	-	6 (4)
endovascular bifurcated graft	4 (2) ©	160 (94)
procedure aborted	1 (1) ©	-
Distal anastomosis – no. (%)		
aorto-aortic graft	104 (60)	3 (2)
other:	69 (40)	165 (96)
aorto-biiliac	58	159
aorto-iliac/femoral	8	6
aorto-bifemoral	3	-
procedure aborted/converted	1 (0.6) ©	3 (2)
Internal Iliac Artery Status – no. (%)		
Postoperative relative to preoperative patency ¥		
Unchanged	167 (96)	142 (83)
One of two patent lost or sacrificed	6 (3)	25 (15)
One of one patent lost or sacrificed		1 (1)
Both lost or sacrificed	1 (1)	3 (2)
Type of endograft used – no. (%)		
Zenith, Cook Inc.	2 ©	57 (34)
Talent, World Medical/Medtronic	3 ©	46 (27)
Excluder, W.L. Gore and Assoc. Inc		37 (22)
Other §		30 (18)

© Crossovers from open to endovascular repair.

† One crossover from endovascular to open repair and one immediate conversion due to access problems of an endovascular bifurcated graft.

‡ One immediate conversion due to access problems of an endovascular monoiliac graft and one due to failed deployment of an endovascular bifurcated graft.

¥ Two patients (one OR and one EVAR) were not at risk for change as bilateral internal iliac arteries were occluded preoperatively.

§ Other endografts used : AneuRx, Medtronic (N=12); Quantum LP, Cordis Corp. (N=8); Ancure, Guidant-EVT (N=5); Lifepath, Baxter Healthcare Corp. (N=4); Endologix, Bard/Impra N=1).

group, as compared with 17.0 percent of patients in the endovascular-repair group (P<0.001).

Table 3 shows the main surgical and postoperative data. As compared with open repair, endovascular repair resulted in a significantly shorter duration of surgery (P<0.001), less blood loss (P< 0.001) and blood replacement (P<0.001), a lower rate of use of postoperative mechanical ventilation (P<0.001), less of a change in the

hematocrit (P<0.001), a shorter stay in the medium care unit and intensive care unit (P<0.001), and a shorter hospital stay (P<0.001).

- ***Endpoints and Adverse Events***

  The operative mortality rate was 4.6 percent in the open-repair group (8 of 174 patients; 95 percent confidence interval, 2.0 to 8.9 percent) and 1.2 percent in the endovascular-repair group (2 of 171 patients; 95 percent confidence interval, 0.1 to 4.2 percent), resulting in a risk ratio of 3.9 (95 percent confidence interval, 0.9 to 32.9; P=0.10) (Table 4). The combined rate of operative mortality and severe complications was 9.8 percent in the open-repair group (17 of 174 patients; 95 percent confidence interval, 5.8 to 15.2 percent) and 4.7 percent in the endovascular-repair group (8 of 171 patients; 95 percent confidence interval, 2.0 to 9.0 percent), resulting in a risk ratio of 2.1 (95 percent confidence interval, 0.9 to 5.4; P=0.10). The combined rate of operative mortality and moderate or severe complications was 23.6 percent in the open-repair group (41 of 174 patients; 95 percent confidence interval, 17.5 to 30.6 percent) and 18.1 percent in the endovascular-repair group (31 of 171 patients; 95 percent confidence interval, 12.7 to 24.7 percent), resulting in a risk ratio of 1.3 (95 percent confidence interval, 0.9 to 2.0; P=0.23).

  Table 4 shows the rates of operative complications according to class and grade for the two groups. As compared with endovascular repair, open repair resulted in a higher rate of moderate and severe systemic complications as well as a higher rate of severe complications. The majority of the difference was due to a higher rate of pulmonary complications in the open-repair group (10.9 percent vs. 2.9 percent). Local–vascular and implant-related complications tended to be more frequent after endovascular repair than after open repair, but the difference was significant only for moderate or severe complications. There were no significant differences between the groups in the rate of local–nonvascular complications.

■ DISCUSSION

When taken together, the findings of this randomised trial comparing open and endovascular aneurysm repair suggest that in patients who qualify for either procedure, endovascular repair is preferable to open repair over the first 30 days after the procedure.

To clarify these findings, some issues need to be addressed. The size of the study group was chosen so that we could demonstrate at least a 10 percent absolute difference in the primary outcome. Owing to time restrictions imposed by the sponsor, the ultimate size of the patient group was 12 percent lower than anticipated. In addition, although our estimate of a 20 percent rate of the primary end point after open repair was accurate (23.6 percent had such an end point), the rate after endovascular repair turned out to be higher than expected (18.1 percent, rather than 10 percent). When designing the trial, we anticipated that the rate of moderate complications after open repair would be considerable. To avoid overlooking a significant difference in the outcome accounted for by differences in the

Table 3. Surgical and Postoperative Data, According to Treatment.

Variable	Open Repair (N=174)	Endovascular Repair (N=171)	p-value
Duration of surgery – min (mean)	151	135	<0.001
Median (Interquartile Range)	150 (120-170)	120 (105-150)	
Estimated blood loss – ml (mean)	1654	394	<0.001
Median (Interquartile range)	1500 (900-2300)	250 (100-500)	
Autologous blood returned – ml (mean±SD).	486±482	– ¥	
Median (Interquartile range)	420 (0-726)	–	
Homologous blood transfused – units (mean)	0.44	0.09	<0.001
Median (Interquartile range)	0 (0-0)	0 (0-0)	
Intraoperative blood transfusion – % (95% CI)°	72 (64-78)	6 (3-11)	<0.001
Homologous blood products used – % (95% CI) †	21 (15-28)	4 (2-9)	<0.001
Intravenous Contrast – ml (mean±SD).	– ©	167±63	
Median (Interquartile range)	–	150 (120-200)	
Total fluoroscopy time – min (mean±SD).	– ©	25±18	
Median (Interquartile range)	–	21 (14-28)	
Duration of MCU or ICU stay ‡ – hours (mean)	72	16	<0.001
Median (Interquartile range)	23 (21-47)	3 (0-20)	
Postoperative mechanical ventilation – % (95% CI)	51 (43-58)	6 (3-10)	<0.001
Duration of postop. mech. ventil. – hours (mean)	34	5	<0.001
Median (Interquartile range)	1 (0-6)	0 (0-0)	
Duration of hospitalization – days (mean)	13	6	<0.001
Median (Interquartile range)	10 (8-15)	4 (3-6)	
Hematocrit change – L/L †† (mean)	0.09	0.07	<0.001
Median (Interquartile range)	0.09 (0.05-0.12)	0.07 (0.04-0.10)	
Decrease of 20% or more – % (95% CI)	53 (44-61)	35 (27-43)	<0.002
Creatinin change ‡‡ (mean)	-0.5	-5.4	0.93
Median (Interquartile range)	7 (-6-17)	7 (-6.3-10)	
Increase of 20% or more – % (95% CI)	13 (8-19)	13 (8-20)	1.00

* Absolute difference of means.

¥ Autologous blood was returned in 3 patients who were converted from endovascular repair to open repair: 412, 700, and 1000 ml.

° CI=Exact Confidence Interval.

© In 5 patients who crossed-over from open to endovascular repair the volume of intravenous contrast used was: n/a, 120, 129, 200, and 200 ml; and the total fluoroscopy time was: n/a, 13, 37, 39, 40 min.

† Homologous blood products: Packed cells; Fresh frozen plasma; Cryoprecipitate; Platelets.

‡ Medium Care Unit (MCU) or Intensive Care Unit (ICU) stay included recovery room stay.

†† Hematocrit change (preoperative minus postoperative [day1]) in L/L: OR: 140 (80%) pairs available; EVAR 136 (80%) pairs available.

‡‡ Creatinin change (preoperative minus postoperative [day2]) in – mol/L: OR: 161 (93%) pairs available; EVAR 134 (78%) pairs available.

rate of moderate complications, we incorporated these into the combined primary end point. Many of the complications included in the Society for Vascular Surgery/International Society for Cardiovascular Surgery definition of moderate complications are important for the postoperative care of patients with abdominal aortic aneurysm and for the assessment of cost-effectiveness. However, after an analysis of all moderate complications, the outcome adjudication committee

concluded that these complications were unlikely to have an appreciable effect on clinical decision making.

As compared with open repair, endovascular repair resulted in significantly better perioperative outcomes, such as a lower rate of systemic complications (mainly pulmonary), less blood loss, a briefer duration of surgery, a lower rate of use of postoperative mechanical ventilation, and shorter hospital stays, all reflecting the less invasive nature of the endovascular approach. These results are consistent with those of previously reported series and systematic reviews.[8-15] This advantage, in combination with a near-significant advantage of endovascular repair over open repair in terms of operative mortality and combined operative mortality and severe complications, makes a compelling case for endovascular repair. The risk ratio for operative mortality was 3.9 for open repair as compared with endovascular repair, with a 95 percent confidence interval of 0.9 to 32.9.

We are aware of three other randomised trials comparing open repair with endovascular repair: the Endovascular Aneurysm Repair (EVAR-1) trial in the United Kingdom, the Anévrisme de l'aorte abdominale: Chirurgie versus Endoprothèse (ACE) trial in France, and the Open versus Endovascular Repair (OVER) trial in the United States. Whereas the last two trials are ongoing, the results of the EVAR-1 trial have been published recently and are similar to our results.[24] Our trial and the EVAR-1 trial are almost equivalent in terms of patient selection (patients with low surgical risk) and outcome criteria. Combining the results of the two trials yields the most accurate approximation of the risk ratio for in-hospital death to date: an operative mortality of 5.8 percent in the open-repair group (40 of 690 patients; 95 percent confidence interval, 4.2 to 7.8) and of 1.9 percent in the endovascular-repair group (13 of 702 patients; 95 percent confidence interval, 1.0 to 3.2), resulting in a risk ratio of 3.1 (95 percent confidence interval, 1.7 to 6.2).

Although our results for endovascular repair compare well with those in the literature, there is some variation in reported operative mortality rates after open repair among our randomised trial and the randomised EVAR-1 trial, historical and recent population-based studies,[9,10,25] and the FDA phase 2, pivotal, concurrent, controlled endograft trials.[12-15] Before the endovascular era, population-based series reported operative mortality rates of approximately 8 percent,[25] whereas recent nationwide or statewide series have reported rates of approximately 4 percent.[9,10] This difference can be explained by the acceptance of a larger proportion of high-risk patients for open repair as the only available option in the older series. Operative mortality rates in the open-repair (control) groups in the FDA phase 2 trials ranged from 0 to 2.7 percent, but these were highly selected patients. The recent population-based series with an operative mortality of approximately 4 percent can be considered a valid representation of the true operative mortality rate for open repair and compares well with the results of our randomised trial of patients with low surgical risk. It is hard to predict whether the overall population-based mortality associated with aneurysm repair would decrease with the widespread use of endovascular repair, since its use in a broader range of patients might diminish some of the benefits that we and others have identified.[9,26]

Patients in our trial had to be eligible for either operation in order to undergo randomisation. Consequently, our findings may not be generalizable to patients

Table 4. Operative Complications, According to Treatment Group.

	Open N=174		EVAR N=171		Risk Ratio (95% CI)	P value
	n	(%)	n	(%)		
Endpoints†						
Operative mortality	8	4.6	2	1.2	3.9 (0.9-32.9)	0.10
Operative mortality and severe morbidity	17	9.8	8	4.7	2.1 (0.9-5.4)	0.10
Operative mortality and moderate/severe morbidity	41	23.6	31	18.1	1.3 (0.9-2.0)	0.23
Complications ††						
SYSTEMIC						
moderate and severe	46	26.4	20	11.7	2.3 (1.4-3.8)	<0.001
severe	19	10.9	6	3.5	3.1 (1.3-9.1)	0.01
Cardiac	10	5.8	9	5.3		
severe	2		3			
Pulmonary	19	10.9	5	2.9	3.7 (1.5-11.9)	0.005
severe	8		2		3.9 (0.9-32.9)	0.10
Renal	2	1.2	2	1.2		
severe	1		0			
Cerebrovasc/spinal cord	2	1.2	1	0.6		
severe	2		1			
Ischemic bowel	2	1.2	1	0.6		
severe	2		0			
Other	11	6.3	2	1.2	5.4 (1.4-53.5)	0.02
severe	4		0			
LOCAL/VASCULAR						
moderate and severe	15	8.6	28	16.4	0.5 (0.3-0.9)	0.03
severe	9	5.2	7	4.1	1.3 (0.5-4.0)	0.80
(Anastomotic) hemorrhage	6	3.5	3	1.8		
severe	6		1			
Graft complications	0	0.0	6	3.5		
severe	0		1			
Graft infection	2	1.2	1	0.6		
severe	0		0			
Endoleak intervention	0	0.0	2	1.2		
severe	0		1			
Thromboembolic	2	1.2	2	1.2		
severe	1		0			
Main renal artery obstruction	0	0.0	3	1.8		
severe	0		1			
Arterial or graft obstruction	5	2.9	11	6.4	0.5 (0.1-1.2)	0.13
severe	2		3			
LOCAL/NONVASCULAR						
Wound complications	6	3.5	6	3.5		
severe	2		1			
Iatrogenic bowel perforation (severe)	1	0.6	0	0		

who are not suitable candidates for open repair. These patients frequently have multiple manifestations of advanced atherosclerotic disease and are at increased operative risk. Neither can our data be generalized to patients who are not suitable

for endovascular repair, since these patients are likely to have more challenging anatomy.[7] Moreover, a patient's eligibility for endovascular repair is dependent on the state of device technology. The introduction of fenestrated and branched endografts is expected to increase the proportion of patients with abdominal aortic aneurysm who can be treated by endovascular repair in the near future.[27]

Age is a well-known predictor of mortality after repair of abdominal aortic aneurysm. Open and endovascular repair may yield similar results in relatively young patients at low surgical risk, whereas the latter approach may be particularly advantageous in older and high-risk patients.[28] The size of our trial is not sufficient to permit a meaningful subgroup analysis of the effect of age or coexisting conditions on the difference in outcome between open repair and endovascular repair. Other larger and longer-term trials are needed to explore this issue further. The sponsor of the current trial has funded an extension of the follow-up period for a total of seven years after surgery; thus, our data address only the perioperative issues.

The ultimate decision regarding which type of repair should be used in a given patient with an abdominal aortic aneurysm is based on a number of factors, including the quality of life expected postoperatively, cost-effectiveness, risk of sexual dysfunction, risk of aneurysm rupture, and reintervention rate.[29] These factors must be considered before a final decision is reached. Our results indicate that in patients who are candidates for both techniques, endovascular repair is preferable to open repair, given its lower rates of operative mortality and complications and the significant reduction in the rates of systemic complications.

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Chapter III

■ LOCAL ANESTHESIA FOR ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR

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INTRODUCTION

In all fields of surgery developments have occurred in the direction of minimally invasive techniques to reduce mortality, morbidity, and discomfort to patients. In vascular surgery this direction has been embodied by the technique of endovascular aneurysm repair (EVAR).

Patients undergoing aortic surgery have a higher than average risk of peri-operative cardiac mortality and morbidity than patients undergoing non-vascular surgery.[1,2] Physiologic factors associated with this increased incidence of complications include hemodynamic and metabolic changes, fluid shift and blood loss, increased myocardial oxygen demand secondary to stress from surgery and anesthesia, increase in post-operative platelet reactivity, and prolonged anesthetic time.[3,4] EVAR is performed with minimally invasive techniques and is associated with reduced blood loss and increased hemodynamic stability.[5,6] Two randomized controlled trials have shown that EVAR is associated with reduced mortality and morbidity compared with open techniques.[7,8] Traditionally, however, EVAR is still performed under regional (RA) or general (GA) anesthesia. Since mortality, postoperative complications and length of stay are the consequences of surgical and anesthetic techniques, a change in the latter may contribute to reduce morbidity and costs after EVAR.

Feasibility and small cohort studies reported encouraging results using local anesthesia (LA) in this setting.[9-11] Other authors, however, found no difference in cardiac mortality and morbidity in a retrospective cohort of patients receiving LA or GA.[12] To our knowledge, there are no randomized controlled trials or large prospective cohort studies documenting the role of LA in EVAR.

The aim of this work is to report the results of a prospective continuous cohort of patients treated by EVAR in a tertiary vascular referral center with a unified anesthetic strategy. This was based on the use of LA in all patients, while reserving RA or GA only to those with pre-defined individual- or surgical-specific indications.

MATERIALS AND METHODS

- ***Type of study***

  This is a prospective cohort study of 239 consecutive elective patients treated with EVAR between April 1998 and December 2003 at a tertiary academic vascular center by a single endovascular team. To define the overall pool of patients undergoing abdominal aortic aneurysm (AAA) surgery during the same period, data regarding open repairs were collected retrospectively from hospital records.

- ***Inclusion criteria***

  Surgery was indicated for aneurysms greater than 5 cm in diameter. An aortic aneurysm greater than 4 cm was also an indication for surgery if associated with iliac artery aneurysms greater than 3.5 cm. EVAR was suggested as a treatment option to all patients and indications were based on anatomic considerations and patient's preference.

From April 1998, a unified strategy to treat all elective patients undergoing EVAR under LA was adopted. Absolute exclusion criteria were: need for additional retroperitoneal approach to the aorta or iliac arteries, need for associated abdominal procedures (e.g. umbilical hernia repair), and patient's choice. Relative exclusion criteria were anxiety, groin re-explorations and body mass index (BMI) > 30 kg/m^2 (obese patients). If LA was contra-indicated, the choice between RA or GA was left to the patients' and anesthesiologists' preference.
During the study period, 40 patients underwent EVAR on an emergency basis. The results pertinent to these patients are reported for completeness but excluded from the main analysis.

■ TECHNIQUES

- ***Surgery***
  All patients received a detailed explanation of EVAR under local anesthesia before surgery, and the study was approved by the hospital review board. EVAR was always conducted in an operating room.

- ***Peri-operative measures***
  A peripheral 14 or 16 Gauge venous cannula was inserted in all patients for fluid administration. Cefuroxim was administered intravenously (IV) for antibiotic profylaxis in the operating room. For RA and GA, electrocardiographic monitoring, pulse oximetry, end-tidal CO_2 (maintained at 4-5%) and urine output, were recorded. In patients undergoing general anesthesia, a 20 Gauge radial arterial line and a 14 Gauge double lumen central venous cannula were also used for arterial and central venous pressure monitoring, blood sampling and fluid administration; in these patients a pulmonary artery catheter was used selectively in the presence of severe left ventricular dysfunction or pronounced pulmonary hypertension. Invasive monitoring was rarely used for RA and never for LA. During all loco-regional procedures supplemental oxygen was given.

- ***Local Anesthesia***
  LA was achieved using infiltration with lidocaine 1% (maximum safe dose 4 mg/kg) or bupivacaine 0.5% (maximum safe dose 2 mg/kg) with epinephrine. Intravenous sedation was used occasionally to maximize comfort rather than to provide analgesia. The goal was to maintain patients fully awake, cooperative, and capable of controlling their airways. Pain was treated, when necessary, with fentanyl, 50 – 150 µg IV bolus or occasionally with ramifentanil 0.1 µg/kg/min continuous infusion. In restless or anxious patients, midazolam 0.05 – 0.2 mg/kg IV or propofol 25 – 75 µg/kg/min IV were used. Operative monitoring included continuous electrocardiography, pulse oxymetry, and arterial blood pressure measured with automatic intermittent plethysmography. A central venous line and a Foley catheter were used earlier in the series. With increasing confidence in the technique and shortened operating time, this practice was stopped. The anesthetist and a nurse

with specific training noted signs and symptoms of pain, maintained verbal communication, and kept patients informed about the progress of surgery.
The technique of LA and femoral artery dissection were tailored to maximize patient tolerance. After abdomen and groins were prepped and draped as per routine open repair, the position of the inguinal ligament was traced with a skin marker. A line of five cm was drawn intersecting the inguinal ligament at the level of the femoral artery (two cm above and three cm below). The dermis and subcutaneous fat were firstly infiltrated bilaterally with the local anesthetic agent, but sharp dissection (without use of diathermy) was carried out only in one groin and to the level of Scarpa's fascia. At this point, local anesthetic was infiltrated under this fascia and dissection was stopped and continued in the contralateral groin where the process was repeated. The attention was then returned to the groin dissected first. When the femoral artery was identified, a small amount of local anesthetic was injected in the fascia around the artery and a segment of three cm was controlled with vessel loops. The procedure was then repeated in the contralateral groin.
To minimize ischaemic rest pain caused by occluding the femoral artery, due to clamping and/or prolonged insertion of the introduction device, the following technique of access was used. In the anterior wall of each common femoral artery, two concentric purse string sutures of five to six mm in diameter were applied using 4-0 polypropylene. The purse strings were controlled with Rummel's tourniquets (Figure 1). Catheter access and device insertions were done through the purse strings previously applied without clamping the femoral arteries. In order to avoid discomfort to the patient during insertion of the main delivery sheath, this was advanced slowly in the arterial system. To accurately deploy the stent-graft close to the renal arteries, intra-operative angiography was used. Angiography, however, was done only after the main delivery sheath had been advanced to the level of the first lumbar vertebra. This technique avoided artifacts caused by patient movements during insertion of the device, which may be uncomfortable due to stretching of the iliac artery. As soon as possible the empty sheath of the main device was removed

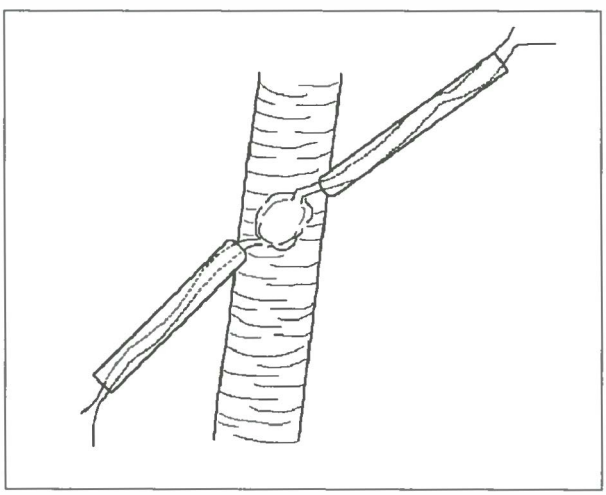

Figure 1. Technique of femoral access with purse string sutures and Rummel's tourniquets in common femoral artery

(i.e. after full deployment and ballooning ipsilaterally), and the purse strings tightened with the Rummel's tourniquet around the guide wire. This was left in place until the contralateral limb of the stent-graft was delivered and a completion angiogram obtained. Temporary closure of the femoral access around the guide wire achieved the effect of restoring normal blood flow to the limb, but allowed re-access of the artery if this became necessary. At the end of the procedure, the artery was repaired by simply tightening the purse string sutures without need for arterial repair. Before closure of the incision, local anesthetic was infiltrated again in both groins. After surgery, patients were cared for in recovery and then transferred to the ward where normal diet and activity was resumed. The urinary catheter, if present, was removed on the day of surgery.

- ***Definition of outcomes***

  The aneurysm morphology and angulations were classified according to the standards suggested by the Society of Vascular Surgery.[13]

  In the post-operative period, cardiac and respiratory investigations were only undertaken if patients became clinically symptomatic. An electrocardiogram or cardiac enzymes were not systematically obtained in all patients. Non-fatal cardiac complications were therefore only those which became clinically apparent: precordial pain, symptoms and signs of pulmonary congestion, ventricular failure, need for diuretic agents. Because of the anticipated low event rate, as a primary outcome we chose a composite outcome including the cluster: all cause mortality, non-fatal cardiac morbidity, respiratory complications and renal failure. Renal failure was defined as need for temporary or chronic dialysis or a greater than 40% increase in pre-operative creatinine.[14] Respiratory complications were defined as the occurrence of pneumonia, respiratory failure requiring pharmacologic intervention, or ventilatory support.

  Secondary outcomes included: additional clinical outcomes (conversion to general anesthesia, wound complications, urinary retention); pre-, intra-, and post-operative use of analgesia; pre- and post-operative haemoglobin and blood product utilization; time related outcomes (fluoroscopy time, contrast volume used, operating time, length of stay in recovery room or intensive care unit, time required to resume oral intake, time to ambulation, and length of stay in hospital).

  Wound complications were classified as minor if they were superficial and did not require debridement.[15]

- ***Statistical analysis***

  Data were prospectively collected in an Excel spread sheet (Microsoft Corporation, USA). Summary for continuous variables are expressed as mean ± standard deviation. Categorical variables were analyzed with Pearson Chi-Square test and continuous variables were analysed with Student's t test (normal distribution) or Mann-Whitney U test (skewed distribution). Differences between groups with more than two factors were analyzed with the Kruskal-Wallis test. To analyze known and unknown variables which affect outcomes over time for types of anesthesia, the Cuzick test was used, because it is more powerful than the Wilcoxon rank-sum to detect differences between more than two groups of data.[16] All the analyses were

two-tailed and P<.05 was considered statistically significant. Data were analyzed using SPSS 11.0 (SPSS, Chicago, IL, USA) and Arcus Quickstat, Biomedical version 1.0.

Patients requiring other interventions than aneurysm repair (e.g. umbilical hernia) or retroperitoneal approach for access were excluded (eight in the GA group, two in the RA group, and one in the LA group) from the comparison of time-related outcomes (operating time, stay in recovery or hospital, resumption of oral intake and ambulation, post-operative analgesia).

Table 1 *Demographics and co-morbidities of patients undergoing abdominal aortic aneurysm repair*

	EVAR‡ (N=239)	Open AAA Repair‡‡ (N=130)	P
Age, mean ±SD*	70 ± 7	69 ± 8	.13
Female sex, n (%)	11 (5%)	21 (16%)	<.001
Body Mass Index, kg/m² ±SD*	27 ± 3	26 ± 4	.07
Previous abdominal procedures, n (%)	37 (15%)	17 (13%)	.6
ASA† Score, n (%)			
I	13 (5%)	3 (2%)	
II	102 (43%)	49 (38%)	
III	113 (47%)	73 (56%)	
IV	11 (5%)	5 (4%)	
Mean ±SD*	2.5 ± 0.7	2.6 ± 0.6	.1
SVS-ISCVS risk score††, n (%)[17]			
Diabetes	21 (9%)	5 (4%)	.08
Tobacco use	116 (49%)	78 (60%)	.04
Hypertension	113 (47%)	83 (64%)	.003
Hyperlipidemia	92 (38%)	45 (35%)	.4
Cardiac disease	118 (49%)	81 (62%)	.02
Carotid disease	13 (5%)	19 (15%)	.003
Renal disease	25 (10%)	23 (18%)	.05
Obstructive lung disease	68 (28%)	40 (31%)	.7
Aneurysm size in mm, mean ±SD*	58.4 ±9.2	62.2 ±13.7	.002

‡ Endovascular Aneurysm Repair;
‡‡ Abdominal aortic aneurysm;
* Standard Deviation;
† American Society of Anaesthesiology classification;
†† Society of Vascular Surgery – International Society of Cardiovascular Surgery, North American Chapter.

■ RESULTS

The demographics, co-morbidities and indications for surgery (aneurysm size) in patients undergoing EVAR and open AAA repair are summarized in Table 1. This offers the denominator of the overall pool of aneurysms treated during the study period. The diameter of aneurysms was smaller, women were fewer, and risk factors

Table 2 Types of endoprostheses used

	Type of Anesthesia		
	Local N (%)	General N (%)	Regional N (%)
Excluder†	34 (74)	6 (13)	6 (13)
Quantum‡	12 (92)	-	1 (8)
Talent††	34 (68)	7 (14)	9 (18)
Vanguard*	17 (52)	13 (39)	3 (9)
Zenith**	73 (75)	12 (12)	12 (12)
Total	170 (71)	38 (16)	31 (13)

† Excluder™ (W.L. Gore, Flagstaff, AZ, USA);
‡ Quantum™ (Cordis, Johnson and Johnson, Fort Lauderdale, FL, USA);
†† Talent™ (World Medical/Medtronic Corp., Sunrise, FL, USA);
* Vanguard™ (Boston Scientific Corp., Waterston, MA, USA);
** Zenith™ (Cook, Bloomington, IN, USA)

(tobacco use, hypertension, cardiac and carotid disease) less prevalent in the EVAR group compared with the open group.

In patients undergoing endovascular aneurysm repair, 5 different types of stent-grafts were used and implanted according to their instructions for use (Table 2). The type of graft used differed in the three groups of patients receiving EVAR with different anesthetic techniques ($F = 7.8$, df 2; $P = .02$). Table 3 illustrates the demographics and risk factors in these three groups. Statistically significant differences were found for age (the GA group was younger) and for gender (females were less represented in the LA group). The mean BMI and hyperlipidemia were significantly lower in the LA group, but there were no differences with respect to other risk factors. Table 4 describes the aneurysm-related variables. There were no differences in neck angulations and distribution of Grade I and III aneurysms between groups, but there were fewer grade IIA and more grade IIB aneurysms in the GA group. Table 5 shows the different reasons for exclusion from LA in the RA and GA groups. With respect to the composite primary outcome LA was associated with a statistically significant lower incidence of complications compared with GA ($P<.001$). The difference between LA and RA, and RA and GA, was not significant ($P=.054$ and $P=.053$, respectively). Table 6 summarizes the results of the clinical outcomes. There were more respiratory complications in the GA group, and fewer renal complications in the LA group. Wound complications were all minor and equally distributed between the three groups. They included seromas and hematomas which did not require intervention. In two patients treated with LA an additional angiogram was required because the patient moved just before graft deployment.

LA was used as planned in 168 of 170 patients (99%). In one patient, early in the series, conversion to GA was required because of an iliac dissection which occurred during introduction of the delivery sheath. Access had to be regained through a retroperitoneal approach. In a second patient, conversion to GA was necessary because of anxiety. There was no significant difference in the number of patients treated with GA or RA (38 and 31 respectively, $P=.96$), but more patients were

Table 3 Demographics of patients undergoing EVAR‡ stratified according to the type of anesthesia

	Type of Anesthesia			
	Local (N=170)	General (N=38)	Regional (N=31)	P
Age, mean ±SD*	70.7 ±7.3	66.7 ±7.9	70.8 ±6.3	.02
Female sex, n (%)	3 (2%)	4 (11%)	4 (13%)	.004
Body Mass Index, kg/m²	26.0 ± 3.2	28.0 ± 3.4	28.5 ± 2.7	<.001
Previous abdominal procedures, n (%)	23 (14%)	7 (18%)	7 (23%)	.4
ASA† Score, n (%)				
I	9 (5%)	3 (8%)	1 (3%)	
II	71 (42%)	16 (42%)	15 (48%)	
III	83 (49%)	15 (40%)	15 (48%)	
IV	7 (4%)	4 (11%)	0	
Mean ±SD*	2.5 ±0.7	2.5 ±0.8	2.5 ±0.6	.9
SVS-ISCVS risk score††, n (%)[17]				
Diabetes	14 (8%)	6 (16%)	1 (3%)	.2
Tobacco use	76 (45%)	21 55%)	19 (61%)	.2
Hypertension	75 (44%)	20 (53%)	18 (58%)	.3
Hyperlipidemia	55 (33%)	21 (55%)	16 (52%)	.01
Cardiac disease	87 (51%)	15 (39%)	16 (52%)	.4
Carotid disease	8 (5%)	4 (11%)	1 (3%)	.3
Renal disease	16 (9%)	5 (13%)	4 (13%)	.7
Obstructive lung disease	50 (29%)	7 (18%)	11 (35%)	.3
Creatinine, mean ±SD* (mmol/L)	110 ± 22	110 ± 27	111 ± 32	.7

‡ Endovascular Aneurysm Repair;
* Standard Deviation; †American Society of Anaesthesiology classification;
†† Society of Vascular Surgery – International Society of Cardiovascular Surgery, North American Chapter

Table 4 Anatomic characteristics of aneurysms treated with EVAR

Classification †† [13]	Type of Anesthesia			
	Local (N=170)	General (N=38)	Regional (N=31)	P
Aneurysm size in mm, mean ±SD*	58 ± 9	59 ± 12	58 ± 8	.9
Grade I, n (%)	13 (8%)	1 (3%)	1 (3%)	.4
Grade IIA, n (%)	110 (65%)	14 (37%)	21 (68%)	<.01
Grade IIB, n (%)	38 (22%)	19 (50%)	7 (23%)	<.01
Grade III, n (%)	7 (4%)	4 (11%)	1 (3%)	.2
Grade IV, n (%)	2 (1%)	0	1 (3%)	.5
Tortuosity of the aorta, n (%)				
180-150	151 (89%)	28 (74%)	26 (84%)	.06
150-120	16 (9%)	10 (26%)	5 (16 %)	.08
<120	3 (2%)	0	0	.5

†† Society of Vascular Surgery – International Society of Cardiovascular Surgery, North American Chapter

Table 5 Reasons for exclusion from local anesthesia

	Type of Anesthesia	
	General (N = 38)	Regional (N = 31)
Patient's choice	14	15
BMI > 30 kg/m²	11	14
Technical reasons		
Additional procedure	3‡	2‡‡
Retroperitoneal approach	5	0
Previous groin surgery	5	0

‡ 2 umbilical hernias, 1 iliofemoral cross over bypass; ‡‡ profundaplasty

Table 6 Clinical outcomes

	Type of Anesthesia			
	Local (N=170)	General (N=38)	Regional (N=31)	P
All cause mortality, n (%)	0	1 (3%)	0	.07
Cardiac mortality, n (%)	0	1 (3%)	0	.07
Non-fatal cardiac morbidity, n (%)	2 (1%)	1 (3%)	1 (3%)	.6
Respiratory complications, n (%)	0	5 (13%)	0	<.001
Renal failure, n (%)	0	2 (5%)	1 (3%)	.02
Pre-operative creatinine (mmol/L), mean ±SD	110 ± 22	110 ± 27	111 ± 32	.7
Post-operative creatinine (mmol/L), mean ±SD	108 ± 26	111 ± 36	122 ± 68	.9
Wound complications, n (%)	12 (7%)	2 (5%)	6 (19%)	.06
Urinary retention, n (%)	6 (4%)	2 (5%)	2 (6%)	.7

Table 7 Post-operative use of analgesia (during hospital stay)

	Type of Anesthesia						
	Local (N=170)		General (N=38)		Regional (N=31)		P
Analgesic agent	n (%)	Dose (mg)	n (%)	Dose (mg)	n (%)	Dose (mg)	
Piritramide (im)	10 (6)	54 ± 26	16 (42)	85 ± 20	7 (23)	89 ± 22	<.001
Paracetamol (po)	109 (64)	6000 ± 2658	18 (47)	8000 ± 1571	22 (71)	8000 ± 1526	<.02
Diclofenac (po)	1 (1)	300	0		2 (6)	300	.2
None	50 (29)		4 (11)		0		<.001

im = intra-muscular ; po = per os

treated with LA (n=170) than with RA (P<.001) or GA (P<.001), respectively. Analysis of trend showed a statistical difference in the pattern of type of anesthesia administered over the six years period (P=.003) in favor of an increased number of

Table 8 Time related outcomes

	Type of Anesthesia			
	Local (N =169)*	General (N = 30)*	Regional (N = 29)*	P
Operating room time, minutes	109 ± 30	139 ± 48	100 ± 20	<.001
Length of stay				
Intensive care unit, minutes	0	1316 (n=2)	0	<.001
Recovery, minutes	96 ± 103	234 ± 288	160 ± 199	<.001
Hospital#, days	3.6 ± 3.4	5.4 ± 3.3	5.2 ± 8.4	<.001
Time to ambulation, days	1.0 ± 0.3	2.1 ± 2.2	1.4 ± 1.3	<.001
Time to regular diet, days	0.4 ± 0.6	2.1 ± 2.3	1.0 ± 0.9	<.001

* Excluded patients because of additional abdominal procedures: one in the LA group; eight in the GA group, and two in the RA group; # including pre-operative admission day

LA associated with a reduction in GA (Figure 2). The significance of this trend, however, disappeared when the data were analyzed excluding the first year of the study.

Premedication with benzodiazepines was used in 89% of patients operated upon with GA, 58% with RA, and 59% with LA, respectively (P=.30). During surgery IV analgesia or sedation was used in 13% of patients operated upon with LA. Discomfort during dissection of the groins, during introduction of the main delivery sheath, and nausea or anxiety was experienced by 16 (9%), 18 (11%), and 2 (3%) of patients operated with LA. Table 7 summarizes the type and amount of post-operative use of analgesic medications in the three groups. There was a difference in post-operative analgesia requirement in favor of the LA group compared with the

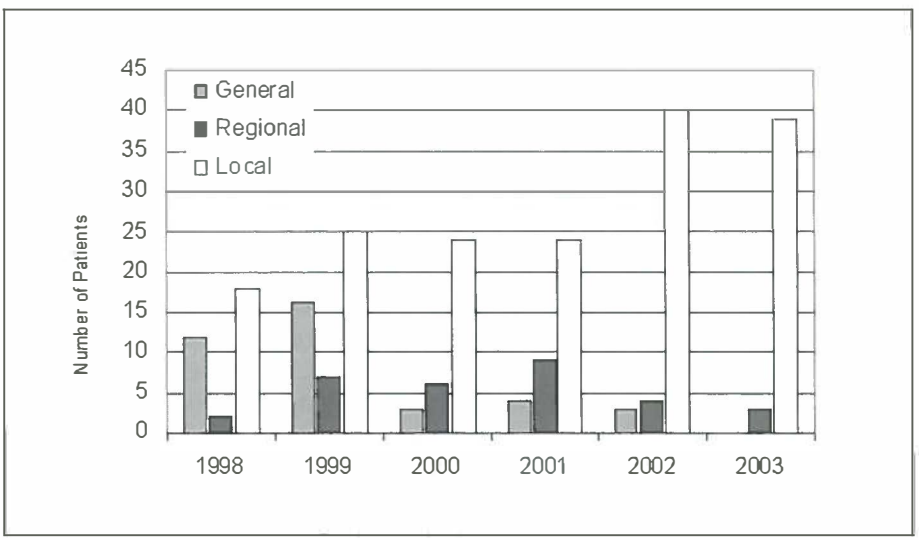

Figure 2. Distribution of types of anesthesia over time

RA and GA group (P<.001). The proportion of patients that did not require analgesic agents post-operatively was highest in the LA group (difference with GA, P<.001; difference with RA, P<.002).
Transfusion of blood products was not required in any patient undergoing EVAR. Fluoroscopy time was greater in the GA group (27.1 min ± 19.8) compared with the RA (10.9 min ± 8.8, P<.001), and the LA (11.0 ± 10.2, P<.001)) groups. Similarly, the total volume of contrast was significantly higher in the GA group (187 ± 76), compared to the RA (143 ± 48, P<.008), and LA (148 ± 49, P<.001) groups. Operating time including anesthesia time, and length of stay in intensive care, were significantly shorter in the LA and RA group, compared with the GA group. Length of stay in hospital, in recovery room, and time to ambulation and regular diet was significantly shorter in the LA group compared with the GA and the RA group (Table 8).
A total of 40 emergency aneurysms (25 acute ruptured, 15 acute non-ruptured) were treated with EVAR (11% of the entire population of aneurysms treated during the study period). In this group EVAR was completed with LA in 33 patients (83%), and survival was 88%. 18,19

■ DISCUSSION

In this study, 70% of elective aneurysms were treated with an endovascular repair and 70% of these were operated upon with LA. RA or GA were reserved only for selected patients. Two patients in the LA group (1%) were converted to GA, one because of an intra-operative complication and one because of anxiety.
Patients undergoing open repair had a greater number of risk factors compared with those undergoing EVAR. There was however, no difference with respect the ASA classification. These findings may be explained by the high risk patients referred to our centre (Table 2) and by the insensitivity of the ASA classification in defining cardiac risk and cardiac complications.[2,20] There were fewer women in the EVAR group reflecting gender differences in anatomical suitability for endovascular repair, including arterial access. The size of aneurysms operated in the open group was also larger than in the EVAR group. This may be explained by the fact that larger aneurysms have also other anatomic characteristics (for example short, conical, or angulated necks) which renders them unsuitable for endovascular surgery.[21]
The anesthetic strategy used in this study generated three distinct groups of patients through the inclusion and exclusion criteria process. These three groups are not directly comparable. There was also a difference with respect to the type of grafts used. This reflected the availability of endoprostheses over time rather than an effect of the grafts on the ability to use LA. Risk factors and anatomic characteristics of the aneurysms were similarly distributed among patients receiving EVAR with different anesthetic techniques (LA, RA, GA), except for hyperlipidemia and BMI which were more represented in the GA and RA groups. The population in the GA group was also younger and exhibited a higher incidence of pre-operative renal failure. Although this difference did not reach statistical significance, it may explain

why renal failure was more prevalent in these patients. The combined incidence of mortality, non-fatal cardiac morbidity, respiratory complications and renal failure was lower in the LA group compared with the GA group. Overall mortality for EVAR however was 0.4%, in keeping with the results of randomized controlled trials,, and not different in the three groups.[7,8]

Patients operated with GA spent significantly longer time in the operating room, in the recovery room, and in hospital compared with those operated with LA and RA. Since we have excluded from this analysis those patients who received adjunctive procedures (e.g. retroperitoneal exposure, repair of umbilical hernia) these differences are plausible. Blood losses, volume of ionized contrast and exposure to radiation were also greater in the GA than in the LA and RA groups. The reasons for these differences are unclear: random events, greater complexity of patients operated with GA, type of endoprosthesis used, or a more relaxed approach to surgery when patients are operated upon under GA are among the possible explanations. The use of post-operative analgesia was reduced in the LA group compared with the other two groups. This may be attributed to a prolonged beneficial effect on pain caused by the infiltration of LA or to a difference in the technique of dissection when patients are operated upon with LA.

Patients operated with LA could often be discharged the first postoperative day. However, in our institution the policy was, to discharge patients treated with EVAR only after a CT scan of the abdomen. This contributed to an average hospital stay (including a pre-operative admission day) for these patients of 3.6 days. At present, however, all patients, regardless the type of anesthesia, are routinely discharged on day one, except if complications occur.

The use of LA in EVAR was described in small non-consecutive feasibility studies.[9-11] Aadahl et al. reported a cohort study of 21 patients treated with EVAR under spinal anesthesia with one post-operative mortality, one myocardial infarction and one pneumonia.[22] De Virgilio et al. reported a retrospective study of 71 patients treated with LA compared with 158 patients treated with GA.[12] No differences in cardiopulmonary complications were identified between the LA group (19%, 95% confidence interval 12 - 29%) and the GA group (13%, 95% confidence interval 8-20%). Patients in the LA group were older and had a greater number of risk factors. The interpretation of this study is, however, limited by the retrospective design, the difference in risk factors between the two groups, and because the criteria used to chose LA and GA were not defined a priori.

Our findings suggest that local anesthesia is feasible and offers advantages in patients who are not obese, do not require additional procedures, had no previous surgery in the inguinal region, and undergo standard EVAR. A potential advantage of LA is also the fact that overstretching the arterial system by the delivery sheath induces discomfort which alerts the physician of the risk of injury or rupture.

The inference drawn from our results is strengthened by the prospective design, the unified strategy used and the large number of patients included. Biases are, however, inherent to cohort studies of this type and the direction is often unpredictable. This is demonstrated by the fact that in spite of predefined criteria for the use of different types of anesthesia, fewer patients received LA during the first year of the study.

We are convinced that a detailed information and preparation of the patient, careful dissection, slow insertion of the main delivery sheath, early restoration of blood flow to the lower extremities, and a short operating time (usually within two hours) are necessary in order to achieve good results with LA.

■ CONCLUSIONS

This study demonstrates that in tertiary centres with extensive experience in EVAR, LA is well tolerated in most patients and is associated with few systemic complications, a short operating time and fast recovery from surgery.

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Chapter IV

FREQUENCY AND OUTCOME OF RE-INTERVENTIONS AFTER ENDOVASCULAR REPAIR FOR ABDOMINAL AORTIC ANEURYSM: A PROSPECTIVE COHORT STUDY

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INTRODUCTION

Since the introduction of endovascular aneurysm repair (EVAR) by Parodi in 1991, the technique has been embraced as a viable alternative to open repair.[1] Reported advantages of EVAR are the lower mortality and morbidity, and the rapid recovery.[2,3] The EUROSTAR registry reported a 30-day mortality of 2.5% in a series of 4392 patients.[4] EVAR, however, is associated with late complications such as migration of the prosthesis, endoleaks, endograft occlusion, and even rupture.[5-15] Re-interventions to preserve the function of the endograft are reported in 10 to 34% of cases.[5,8,12,14-19] However, the frequency of re-interventions after EVAR, the burden of single and multiple procedures for the individual patient, and the overall outcomes of these re-interventions all require further investigation.
The purpose of this study was to describe the long-term results of EVAR in a consecutive cohort of patients treated in a single academic institution, and to report the frequency, type, and outcome of re-interventions.

Table 1 Type of endoprosthesis used

	Primary Intervention N (%)	Re-intervention N (%)
Excluder†	56 (18)	2 (4)
Quantum‡	12 (4)	-
Talent††	52 (17)	6 (12)
Vanguard*	68 (22)	32 (47)
Zenith**	120 (39)	7 (6)
Total patients	308	47

† Excluder™ (W.L. Gore, Flagstaff, AZ, USA)
‡ Quantum™ (Cordis, Johnson and Johnson, Fort Lauderdale, FL, USA)
†† Talent™ (World Medical/Medtronic Corp., Sunrise, FL, USA)
* Vanguard™ (Boston Scientific Corp., Waterston, MA, USA)
** Zenith™ (Cook, Bloomington, IN, USA)

MATERIAL AND METHODS

- ***Patients***
  This is a prospective cohort study of 308 consecutive elective patients treated with EVAR between September 1996 and December 2003 at a tertiary academic vascular centre by a single endovascular team. Surgery was indicated for aneurysms greater than 5 cm in diameter. An aortic aneurysm greater than 4 cm was also an indication for surgery if it was saccular or if it was associated with iliac artery aneurysms greater than 3.5 cm.

- ***Type of endoprosthesis***
  Five different types of stent-grafts were used during the primary procedure (Table 1). In the first 32 patients, we used the only one available device, Vanguard. When

other products were commercially approved, we used them according to a strategy that gave preference to the Talent for large infrarenal necks (>28 mm), the Zenith for short necks (<20 mm), and the Excluder for straight long necks but angulated or small iliac vessels. The most recent device, Quantum, only has been used in 12 patients. A bifurcated stent-graft design was used in 298 patients (96.8%), a tube graft in five patients (1.6%), and an aorto-uni-iliac graft in five patients (1.6%).

- ***Follow up***
  From September 1996 to January 1999, physical examination, duplex ultrasound scanning (DUS), and computed tomography angiography (CTA) or magnetic resonance angiography (MRA) were performed at discharge, at one, and at three months after the intervention; every six months for the first two years, and yearly thereafter. From February 1999 to March 2004 with increasing experience, and as suggested by other authors, the protocol was changed: following an initial CT scan before discharge, patients were followed at one, six and twelve months with physical examination, DUS and a four plain abdominal X-ray.[20,21] CTA or MRA was only used if there was an increase in size of the aneurysmal sac or the suspicion of an endoleak on DUS, or if there was evidence of migration or of compromise of the structural integrity of the stent-graft on the abdominal X-ray.

- ***Definitions***
  In the context of this study, complications refer only to those related to the aneurysm and the stent-graft.
  An endoleak was defined as perigraft blood flow due to an inadequate seal and arising from the proximal or distal attachments of the endograft,[22] from retrograde visceral or lumbar vessels,[22] or from disconnection of modular endografts (type III).[23,24]
  Re-intervention was defined as an endovascular or open surgical intervention performed after the initial EVAR in order to maintain the function or patency of the endograft. When more than one re-intervention was necessary during follow-up, the classification of primary, secondary, and tertiary re-intervention was used.
  Patient re-interventions/follow-up: after EVAR, patients may require multiple procedures during one re-intervention and multiple re-interventions over time. As a measure of the overall impact of EVAR on patients treated with this approach, we introduced the definition of patient re-interventions/follow-up. This refers to the number of re-interventions in separate surgical treatments, divided by the total number of patients entering the follow-up.
  Clinical success of a re-intervention was defined as follows. If a proximal aortic cuff was used, success was defined as disappearance of a type I endoleak, no further downward migration of the prosthesis and no further aneurysmal growth. If a distal extension or a recanalisation of an occluded limb or a bridging stent-graft was used, clinical success was defined as a patent limb without type I or type III endoleak. If embolisation or ligation of side branches was used, clinical success was defined as an aneurysm without type II endoleak or further expansion. Clinical success of cross-over bypasses was defined by a patent graft and successful revascularisation of the ischaemic limb. Clinical success of open conversions was defined as patient survival.

Table 2 Pre-operative SVS-ISCVS risk score in patients treated with EVAR (N= 308).[30]

	SVS-ISCVS Risk Score†			
	0	1	2	3
Co-morbidities (%)				
Diabetes	92	3	4	1
Tobacco use	44	27	24	5
Hypertension	46	33	17	4
Hyperlipidemia	54	27	6	14
Cardiac status	47	26	22	5
Carotid disease	94	3	3	1
Renal disease	87	11	1	1
Pulmonary status	68	17	12	3

† Society of Vascular Surgery – International Society of Cardiovascular Surgery, North American Chapter

An open conversion was defined as a laparotomy with the removal of the endograft and insertion of a bifurcated prosthesis. The term laparotomy implied non-conversion laparotomies only.

- ***Statistics***
  Summary data for continuous variables are expressed as mean ± standard deviation. Data were prospectively collected in an Access database (Microsoft Corporation). Primary outcomes were clinical success, graft patency, and patient survival. Time-to-event variables were studied with Kaplan-Meier survival analysis and comparison of time-to-event curves conducted with Peto log-rank test, using SPSS 11.0 (SPSS, Chicago, IL, USA). A P value less than 0.05 was considered statistically significant.

■ RESULTS

In 308 patients undergoing EVAR, the mean age was 70 ± 11 years and 94% were males. The mean diameter of the aneurysm was 59 ± 9 mm (range 40 to 100 mm). Pre-operative risk factors of the patients are shown in Table 2. One patient required conversion to open repair because of technical reasons, and one died of a myocardial infarction the day after surgery (hospital mortality, 0.3%) leaving a group of 306 patients for analysis of long-term results, of whom none was lost to follow-up.

Patients were followed for a mean of 36 ± 22 months. A total of 126 late complications occurred in 102 patients (33%) (Table 3). However, re-interventions only were performed in 47 patients (15%). There was no difference in demographic and risk factors between patients who did and did not develop complications after EVAR. Details of the primary re-interventions in the 47 patients are shown in Table 4. Re-interventions were performed electively in 31 patients (66%), and on an emergency basis in 16 (34%). In the latter group, surgery was required for either acute limb ischaemia in 14 patients (88%) (nine treated with thrombolysis followed

Table 3 Patients with delayed complications and re-interventions after EVAR

Patients		N (%)
Patients with complications non requiring re-interventions		55 (18)
Number of complications	57	
Type of complication		
migration	25	
kink	5	
type II endoleak†	26	
limb occlusion	1	
Patients with complications requiring re-interventions		47 (15)
Number of complications	69	
Patients without complications		204 (67)
Total patients		306
Total complications	126	

† disappearing within 6 months or without growth of the aneurysm

Table 4 Re-interventions performed in 47 patients.

	N
Single procedure	41
Aortic cuff	5
Extensions†	13
Bridging stent-graft	2
Recanalisation	9
Aortic Palmaz stent	1
Embolisation of IMA	1
Cross over bypass	5
Laparotomy	1
Open conversion	4
Multiple procedures in one session	6
Proximal cuff + extension	3
Extension + embolisation of IMA	1
Bridging stent-graft + embolisation of IMA	1
Bridging stent-graft + extension	1

† In this group are included patients who received 4 wallstents; IMA: inferior mesenteric artery

by additional stenting, and five with a cross over bypass) or acute aneurysm (stent-graft disconnection with type III endoleak in two patients). One of these aneurysms was ruptured and treated with open repair, and the other was an impending rupture and treated with a bridging stent-graft.

After re-interventions, patients returned to the regular follow-up programme. No further problems during follow-up occurred in 32 patients (68%) (i.e. the primary re-intervention was successful). However, in 15 patients, new complications and adverse events occurred. In two patients, re-intervention was not necessary: one because a failed embolisation of the inferior mesenteric artery was not associated with an endoleak on subsequent CT scan, and the second because the occlusion of

Table 5 *Details of patients with complications and with newly arisen problems after initial secondary intervention*

Patient (no.)	Primary reintervention	Complication	Secondary reintervention	Complication	Tertiary reintervention
1	Aortic cuff	Endoleak type II	Laparotomy	-	-
2	Aortic cuff	Endoleak type II	Laparotomy	Disconnection	Laparotomy
3	Aortic cuff + extension	Limb Occlusion	Conversion	-	-
4	Extension	Limb Occlusion	-	-	-
5	Extension	Endoleak type II	Laparotomy	-	-
6	Extension	Migration (P+D)	Cuff + extension	Disconnection	Conversion
7	Extension	Disconnection	Bridging stent-graft	Limb Occlusion	Conversion
8	Bridging	Limb Occlusion†	Cross over bypass	-	-
9	Recanalisation	Migration/kink (D)	Wallstent	-	-
10	Recanalisation	Limb Occlusion	Cross over bypass	-	-
11	Recanalisation	Limb Occlusion	Cross over bypass	-	-
12	Recanalisation	Limb Occlusion	Cross over bypass	Migration (P)	Cuff + Wallstent
13	Embolisation	Technical failure	-	-	-
14	Cross over bypass	Migration (P)	Conversion	-	-
15	Cross over bypass	Migration (P)	Conversion	-	-

P: proximal; D: distal;
† contra-lateral side

a limb of the graft resulted in only mild claudication. The remaining 13 patients required secondary re-interventions (12 single, and one multiple simultaneous procedures), and four patients also required tertiary re-interventions (three single, and one multiple simultaneous procedures). Details of these events are summarised in Table 5. Overall a total of 64 re-interventions were performed in 47 patients for a patient re-interventions/follow-up of 21% (64/306).

Since multiple procedures may be performed during the same surgical session, Table 6 summarises the results in terms of clinical success for the 72 adjunctive manoeuvres performed in 47 patients. The overall clinical success of endovascular re-interventions was 80%. Distal extension stent-grafts were not successful in four of 19 procedures: two occluded and two disconnected. One occluded stent-graft was not treated because, as stated above, it only caused mild claudication; the other resulted in a conversion. The two disconnections led to a conversion, one directly, the second after a bridging stent-graft which occluded 8 months later. Four out of the nine recanalisations with thrombolysis were not successful: in one instance because the limb of the graft could not be reopened, in two because the limb of the stent-graft re-occluded (one at 3 and the other at 30 days), and in one because of a kink in the graft. The first three patients were treated with a cross over bypass and the last with insertion of a Wallstent.

The clinical success of open re-interventions was 96%. All cross over grafts remained patent. In five patients with a type II endoleak, a laparotomy was performed because the aneurysm diameter had increased. After opening the aneurysmal sac, the lumbar arteries were ligated with sutures, and the sac wrapped around the stent-

Table 6 Clinical outcome of all secondary procedures performed in 47 patients

Re-interventions	N (%)	Clinical success N (%)
Endovascular	49 (68)	39 (80)
Aortic cuff	10	10 (100)
Extension	19	15 (79)
Recanalisation	9	5 (56)
Bridging stent-graft	5	4 (80)
Embolisation	3	2 (66)
Palmaz stent	1	1 (100)
Wallstent	2	2 (100)
Open surgical	23 (32)	22 (96)
Cross over bypass	9	9 (100)
Laparotomy	5	4 (80)
Open conversion	9	9 (100)
Total	72	61 (85)

Table 7 Details of open conversions.

Patient (no.)	Stent-graft (type)	Time since EVAR (months)	Previous re-interventions	Indication for conversion	Urgent treatment	Outcome (at 30 days)
1	Vanguard	54	Cuff + extension	Limb Occlusion	No	Survived
2	Vanguard	57	Extension; cuff + extension	Disconnection	No	Survived
3	Vanguard	64	Extension; bridging	Limb Occlusion	No	Survived
4	Vanguard	44	No	Migration (P+D)	No	Survived
5	Talent	27	No	Migration; Limb Occlusion	No	Survived
6	Vanguard	44	No	Migration; Limb Occlusion	No	Survived
7	Vanguard	45	No	Rupture	Yes	Survived
8	Vanguard	41	Cross over bypass	Migration (P)	No	Survived
9	Vanguard	24	Cross over bypass	Migration (P)	No	Survived

P: proximal; D: distal

graft. During follow-up, however, in one of these patients a disconnection between the body of the endoprosthesis and one of the limbs occurred and required additional open treatment (laparotomy, ligation of the contra-lateral limb and cross over bypass). The mean hospital stay of the remaining four patients was 12 days (range, 10-17). Nine patients (3%) underwent open conversion: one because of a ruptured aneurysm, three because the complexity of the problem made endovascular treatment untenable and five after failure or complications associated with a previous endovascular re-intervention (Table 7). Laparotomy was performed with a midline incision and infra-renal clamping was used in seven patients, and temporary supra-renal clamping in two. All nine patients survived and were discharged after a mean of 11 days (range, 10-11).

The cumulative intervention-free survival for the different types of stent-graft used is shown in Figure 1. The only statistically significant difference was found between the Vanguard device and all other types of stent-grafts ($P < 0.05$).

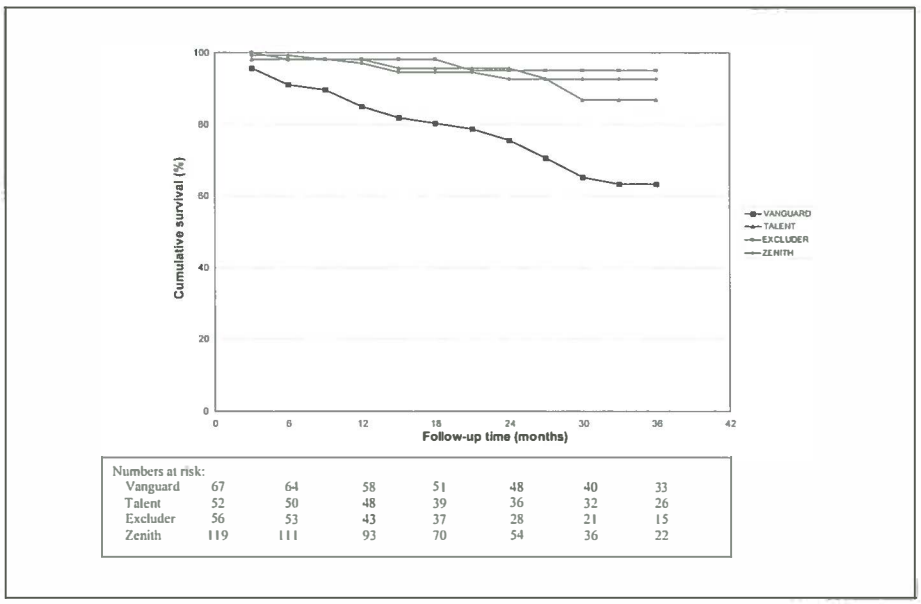

Figure 1. Cumulative intervention free survival rates

None of the 47 patients died after the secondary procedure. Five of them (11%) died of causes not related to the secondary procedure after a mean of 35 months (range 29 to 48).

■ DISCUSSION

This cohort study shows that, in appropriately selected patients, EVAR using predominantly bifurcated prosthesis has an excellent peri-operative success rate with low surgical mortality and conversion (each 0.3%). At 36-month follow-up, 261 patients (85%) had their aneurysm successfully excluded by EVAR, without need for furhter intervention. Re-interventions2 were required in 47 patients (15%), with no mortality. In patients requiring re-intervention, endovascular rescue procedures were possible in 68% with a success rate of 80%; and open re-intervention were necessary in 32% with a clinical success of 96%. Overall 285 of 306 (93%) patients had their aneurysm treated with endovascular procedures alone, and 297 (97%) with a combination of endovascular and open surgery (cross over bypass or laparotomy for closure of endoleaks). Conversion to open aneurysm repair was required in only 3% of the entire cohort of patients. Complications, which did not require interventions, but needed careful surveillance developed in an additional 18% of patients.

The concept of patient re-interventions/follow-up helps to clarify the overall impact of multiple procedures for patients undergoing EVAR. The service impact of repeated procedures is similar if many patients receive one re-intervention or only a few patients receive multiple re-interventions in different sessions. In our series,

EVAR was associated with a low patient re-interventions/follow-up (21%). This also was an expression of the effectiveness of re-interventions after EVAR.

The majority of the elective re-interventions were required because of a persistent endoleak, graft migration, or failure of the aneurysmal sac to reduce in size. The majority of emergency re-interventions (88%) were required for acute leg ischaemia. Only two patients were treated acutely for reasons other than limb occlusion, both because of a prosthetic limb disconnection. The first presented with a ruptured and the second with a symptomatic aneurysm, at 44 and 21 months, respectively, after the primary repair. The first patient underwent open conversion, and the second received a bridging stent-graft, both successful. Retrospectively, it was clear that the abdominal X-ray of the patient with symptomatic aneurysm had shown an initial migration of the contra-lateral limb. At this stage a bridging stent-graft could have been easily inserted preventing the complete dislocation, which required a more complex procedure. This further illustrates the importance of regular and meticulous follow-up after EVAR.

In our experience endovascular re-interventions for problems related to the proximal end of the prosthesis (cuff extensions) were invariably successful, while distal extensions and recanalisation of occluded limbs failed in 21% and 44% of cases, respectively. We believe that the current success of proximal cuff extensions is related to the position of the cuffs very close to the orifices of the renal arteries and to the use of cuffs with supra-renal fixation with hooks and barbs. The relatively high failure rate of distal extensions and recanalisations is secondary to the increased burden of graft material in a narrow lumen environment, and perhaps to the progression of pathology (dilatation, kinking, and calcification) in the native arteries.

The Vanguard device was associated with the most complications. However, 80% of all complications also occurred in the first 100 stent-grafts, suggesting that the learning curve might have played a role in the high incidence of complications observed with the Vanguard device. The learning curve for EVAR depends on measurement issues, choice of size of prostheses and different physical characteristics of the grafts. Even with the increased availability of different devices, we do share the opinion that the ideal graft is yet available and continue tailor the choice of graft based on the aorto-iliac anatomy and the physical characteristics of the stent-graft currently available. Early in our cohort we used the Talent device for large infra-renal necks (>28 mm), since it was the only suitable device. Currently, for large (>28 mm) or short necks (<20 mm) we prefer to use the Zenith device because of its strong suprarenal fixation, and the Excluder device for straight long necks but angulated or small iliac vessels. Even in these hostile iliac arteries we have not observed limb occlusion with an Excluder endograft.

In agreement with other authors, our strategy for management of type II endoleaks is conservative if the aneurysm is shrinking or remains stable.[8,25,26] Laparotomy is performed for an increase in aneurysm size. The aneurysmal sac is opened, the lumbar arteries or the inferior mesenteric artery are suture ligated and the sac wrapped around the endograft. We do not remove the prosthesis at this time since this is a complex, unwarranted procedure. Other treatment options include

Table 8 Literature summary of secondary interventions and open conversions

Author	Publication (year)	No. of patients	Type of graft	Follow-up period (months, mean)	Patients requiring re-interventions† (%)	Open conversions *N* (%)
Ohki et al.[14]	2001	239	Ac, An, Ex, MEGS, V, T, Z	16	10	5 (2.1)
Hölzenbein et al.[12]	2001	166	Ex, St, T, V, Z	18	22	unknown
Faries et al.[5,9]	2002	366	T	7	9	4 (1.0)
Dattilo et al.[8]	2002	362	An, EVT, Ex, MGH, V, Z	18	13	8 (2.2)
Alric et al.[5]	2002	88	Z	21	7	4 (4.5)
May et al.[5;13]	2003	190	An, B, Bx, Ch, EVT, P, T, V, WY	84	34	25 (13)
Parodi et al.[19]	2003	100	V	28	22	-
Sampram et al.[15]	2003	703	Ac, An, Ex, Elx, T, Z	12	14	11 (1.6)
Becquemin et al.[16]	2004	250	An, EVT, Ex, S, T, V	18	27††	11 (4.4)
Present study	-	306	Ex, Q, T, V, Z	36	15	9 (3.0)

† This includes primary, secondary and tertiary re-interventions

†† This is the number of patients, but overall 112 secondary procedures (primary, secondary, tertiary, quaternary) were performed for 45% patient re-interventions/follow-up

Ac Ancure; An Aneurx; B Bard; Bx Baxter; C Chuter; Elx Endologix; EVT Endovascular Technologies; Ex Excluder; MEGS Montefiori Endovascular Graft; MGH Massachusetts General Hospital custom-made graft; P Parodi; Q Quantum; S Stentor; St Stenway; T Talent; V Vanguard; WY White-Yu; Z Zenith.

thrombin or glue injection, coil embolisation, and laparoscopic clipping.[8,12,16,22,27] We have not used any of these adjunct treatments.

The importance of follow-up is underscored by the late acute complications, which may develop after EVAR. Aortic rupture after insertion of endoprosthesis is one dramatic example. This in the EUROSTAR report has been estimated to occur with a frequency of 1% per year. Recognised risk factors for rupture are graft migration, type I and type III endoleaks.[28] However, in our experience, perhaps because of early detection and treatment of complications, EVAR was associated with a rupture rate of only 0.3%. Our initial follow-up protocol required a CT scan at discharge, 1, 3, 6, 12, 18 and 24 months, and yearly thereafter. This was too onerous both for patients and physicians. With data emerging from the EUROSTAR registry suggesting that CT scan imaging could be reduced to annually, and other authors reporting on the role of abdominal X-ray and DUS in the follow-up of EVAR, we felt appropriate to change our strategy.[20,29] We included only a CT scan before discharge, and at 6 and 12 month follow-ups, and thereafter yearly examination using abdominal X-ray and DUS, performed and interpreted by experienced vascular technicians and physicians. Parameters studied at each interim follow-up are the diameter of the aneurysm and the proximal neck, the presence or absence of endoleaks, and the position and integrity of the stent-graft. If any of these parameters are abnormal, a CT scan or an MRA are performed. Problems identified with these imaging techniques may trigger an intervention or, if the problem does not appear to be life or limb threatening, a further follow-up at 6 months. The lack

of temporal trends in the frequency and type of acute complications requiring surgery and the low incidence of aortic rupture after insertion of endoprosthesis are a pragmatic proof of the effectiveness of our follow-up strategy

Bias is inherent to cohort studies of this type, and future development in graft technology may alter the natural history of endoprosthesis. However, strengths of our study include the prospective design, the large number of patients included, the fact that no patients were lost to follow-up, the consistency of events over time, the finding that, with the exception of the Vanguard device, no difference in re-intervention-free survival was identified among different types of devices, and the similarity of results with those identified by other authors (Table 8). For these reasons we feel that our results are realistic and are generalisable to similar tertiary centres taking care of patients with infra-renal aortic aneurysms.

The implication of this work for clinical practice is that a strategy of using bifurcated endoprosthesis in selected patients is effective for the management of infra-renal aortic aneurysms, when the appropriate learning curve has been accomplished and when the type of graft is individualised to the particular aorto-iliac anatomy. Endovascular re-interventions should be preferred when possible, particularly for proximal extension cuffs, which are usually associated with a high success rate. In the management of graft limb complications, thrombolysis and distal endograft extensions also are effective, but a higher failure rate should be anticipated. Finally, our type of follow-up is simple, practically feasible, and it was not associated with increased mortality and morbidity.

In addition to a meticulous description of the indications, techniques, and strategy of follow-up, we suggest that future studies of re-interventions after EVAR include in their results the patient re-interventions/follow-up as an expression of the burden of multiple interventions on patients undergoing this strategy of management of infra-renal aortic aneurysms.

■ CONCLUSIONS

Our findings, derived from a large prospective cohort of patients treated by a single endovascular team at a tertiary vascular centre, confirm that with appropriate surveillance and re-intervention, EVAR can spare an open aneurysm repair in 97% of individuals with suitable aortic anatomy. The burden of repeated procedures to patients (15%) was relatively low. Our simplified follow-up was effective and an integral part of management of aneurysms treated with EVAR, in order to avoid life or limb threatening complications.

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Chapter V

ENDOVASCULAR REPAIR OF ACUTE AAAs UNDER LOCAL ANESTHESIA WITH BIFURCATED ENDOGRAFTS: A FEASIBILITY STUDY

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INTRODUCTION

Operative results for abdominal aortic aneurysms (AAA) have improved substantially during the last 5 decades, with overall mortality now ranging between 4.5% and 7%.[1-3] These improvements can partially be explained by better critical care, management of cardiac function, and better pharmacological support. In contrast to the results of elective surgery, the reported operative mortality rates with acute aneurysms remain high, ranging from 24% to 70%.[4-7]

Endovascular techniques, as developed during the last decade for elective aneurysm repair, are associated with a reduced physiological stress.[8-12] In principle, this approach would be very attractive for treating acute patients, since they are usually already in a compromised condition. However, practical logistics, such as the need for pre-operative measurement and the availability of correctly sized endovascular devices, seem to stand in the way of endovascular treatment in acute cases.

Nevertheless, a few centres have taken up the challenge and published their experience in the endovascular management of acute aneurysms.[13-18] Aorto-uni-iliac grafts were used in most instances to achieve quick exclusion of the aneurysm, but this technique involves a femorofemoral cross over bypass and an occluding stent in the contra-lateral iliac artery. In the main, these patients were treated under general anesthesia.

In view of our substantial experience with local anesthesia in elective endovascular aortic repair (EVAR), we began a study in which acute AAA patients were treated with a modular bifurcated endograft under local anesthesia

METHODS

This study was undertaken with the approval of the Medical Ethical Committee of our institution to investigate the feasibility of EVAR for acute AAA under local anesthesia. Inclusion criteria were a stable, albeit hypotensive condition and anatomical suitability for EVAR.[19] Other requirements for emergent EVAR were the availability of an experienced endovascular team and a correctly sized endovascular device.

The anatomical suitability for endovascular repair was assessed with urgent spiral computed tomography (CT) after the initial diagnosis of AAA was confirmed with an ultrasound scan. To this end, the CT scanner in the emergency department was made available as soon as the patient was admitted. If necessary, when blood-pressure was judged too low during CT or the procedure, a balloon (Reliant®, Medtronic AVE, Santa Rosa, CA, USA) was inserted percutaneously from the left groin over a stiff guidewire and positioned at the level of the first lumbar vertebra to achieve hemostasis and adequate blood pressure.

The endovascular team evaluated suitability for EVAR according to the manufacturer's guidelines: proximal neck length at least 1.5 cm long with < 60o angulation, at least one common iliac artery suitable for fixation (<20 mm diameter), and access vessels large enough to accommodate the introduction systems (usually 20 F and 16 F).

Based on the clinical presentation and the CT findings, two types of acute AAA were distinguished: the symptomatic AAA (SAAA), which is painful but without associated hypotension or retroperitoneal hematoma, and the ruptured aneurysm (RAAA), with hypotension and retroperitoneal hematoma documented on the CT scan.

During the 4-year study period (1998-2001), 163 patients presented at our hospital with acute AAA. In 116 (71%), EVAR was not undertaken owing to unavailability of an endovascular team or device (n = 56), deep shock deemed by the surgeon to warrant immediate surgery (n = 11), and in 49 cases because the on-call team did not consider it.

In the remaining 47 patients, the vascular anatomy was interpreted as unsuitable for endovascular repair in 31 (66%), largely because of an unsuitable proximal neck. These 31 patients were treated surgically, leaving 16 (34%) patients (10% of the population) who underwent EVAR. Of these, four were already undergoing evaluation or on the waitinglist for an endovascular procedure.

Every procedure was performed in an operating room using a mobile image intensifier (OEC 9800, GE Medical Systems, Milwaukee, WI, USA) with digital subtraction angiography and video copy output. Vascular access was obtained via bilateral surgical cutdown in the common femoral arteries. When used, local anesthesia to both groins was achieved with a 50/50 mixture of 1% lidocaine and 0.5% bupivacaine (maximum dose of 60 mL). If necessary, intravenous sedation with midazolam or analgesia with fentanyl was administered by the anesthetist.

All endografts were bifurcated modular devices: Vanguard (Boston Scientific, Natic, MA, USA), Talent (Medtronic World Medical, Sunrise, FL, USA) or, most recently, the Zenith Tri-Fab (William A. Cook Australia, Brisbane, Australia), which is a three-component system that can accommodate all suitable aneurysms.

Mortality was assessed in the surgical and EVAR groups, but in the latter, additional parameters were evaluated, including peri- and post-operative complications, mode of anesthesia, procedural time, bloodloss, transfusion requirements, intensive care unit stay, and hospital stay.

■ RESULTS

Mortality in the entire 163-patient population was 29%; of these 47 deaths, 46 were in the surgical cohort (31% of 147 patients). According to the type of aneurysm, the mortality rates for open repair were 36% (41) among the 115 patients with RAAA, and 16% (5) in the 32 patients with SAAA.

Mortality in the 47 patients evaluated for EVAR was 17%; 7 (23%) of the 31 patients unsuitable for EVAR died (6/23 patients with RAAA and 1/8 with SAAA). In three patients who were unsuitable for EVAR, a balloon was inflated at the level of the first lumbar vertebra under fluoroscopy because of progressive shock. This achieved hemostasis and acceptable blood pressure (>100 mm Hg systolic) before and during anesthesia. All three patients survived the open procedure.

Among the 16 patients who underwent EVAR (table), one (6%) died following conversion to open repair after access failure (calcified vessels blocked sheath

Table Demographic, Aneurym, and Procedural Characteristics

Case	Sex	Age	Aneurysm type	Anesthesia	Stent-graft model	Duration (min)	Packed cell transfusion (units)	Complications	Hospital stay (days)
1	Male	67	SAAA	General	Vanguard	110	0		5
2	Male	86	SAAA	Local	Vanguard	90	0		5
3	Male	63	RAAA	Local	Talent	75	0		6
4	Male	69	SAAA	General	Vanguard	160	0	venous patch	3
5	Male	79	SAAA	General	Talent	100	0		6
6	Female	79	RAAA	Local	(converted)	240	4	deceased	
7	Male	65	SAAA	Local	Zenith	80	0		5
8	Male	79	SAAA	Local	Zenith	110	0		4
9	Male	71	RAAA	Local	Zenith	110	2		7
10	Male	71	RAAA	Local	Zenith	85	0	ischaemic colon	10
11	Male	59	RAAA	Local	Zenith	120	2	(percutaneous)	7
12	Male	75	SAAA	Local	Zenith	130	0		8
13	Male	79	RAAA	Local	Zenith	220	7	laparotomy	11
14	Male	82	RAAA	Local	Zenith	130	0		7
15	Male	83	RAAA	Local	Zenith	110	0	groin hematoma	6
16	Female	81	RAAA	Local	Zenith	90	0	dialysis	22

insertion). Post-operatively, the patient developed ischaemic colitis; although sigmoid resection was performed, she died 12 days later due to multiple organ failure. In the other 15 patients, the endovascular procedure was performed without problems. In none of these cases was a balloon required to prevent further hypotension during the procedure.

Local anesthesia was applied in 12 of the 16 procedures, with intravenous sedation administered in six. Except for the patient converted to open surgery, there was no conversion from local to general anesthesia in the EVAR group. The procedure was well tolerated by the patients.

The median duration of EVAR was 110 minutes (range 75-240, including the additional procedures). Blood loss ranged from 100 to 2800 mL (median 250). Only four patients required blood transfusion during the procedure. In one patient (case 11), the procedure was performed percutaneously to gain time because of hypotension (75/45 mmHg). At the end of the procedure, a cutdown was performed under local anesthesia with intravenous sedation to remove the sheaths. Another patient (case 13) with a huge retroperitoneal hematoma (Figure) was anesthetized after stent-graft implantation so that a midline laparotomy could be performed to evacuate the hematoma. This decision was made at the end of the procedure because the abdomen was distended and an abdominal compartment syndrome was feared. The aneurysm was opened, showing good sealing by the graft and a left laterodorsal frank rupture. The aneurysm sac was then wrapped around the endovascular graft, and the proximal endograft was secured to the aortic wall. In a third patient (case 4), closure of the arteriotomy in the groin required a venous patch taken from the long saphenous vein in the same groin (under local

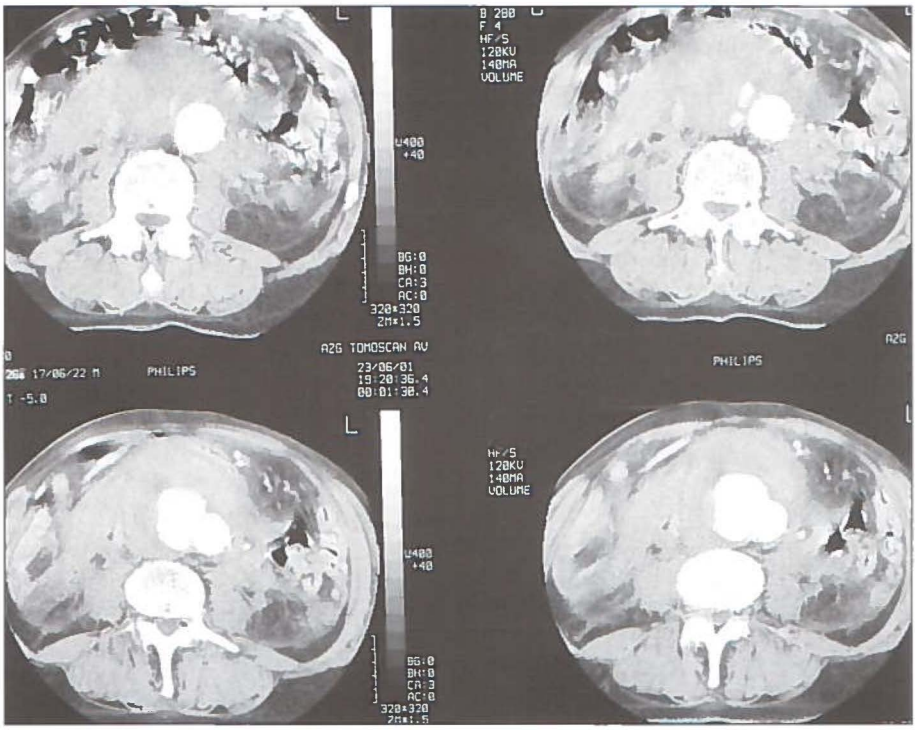

Figure. Pre-operative CT scan showing a ruptured abdominal aortic aneurysm with a large retroperitoneal hematoma

anesthesia). In all, only eight of the 16 patients required admission to the intensive care unit, the others were discharged to the ward from the recovery room.

There were three post-operative complications in the EVAR group. One patient (case 10) developed ischaemic colitis, which was treated conservatively. Both hypogastric arteries were patent but a patent inferior mesenteric artery was blocked by the stent-graft. A second patient (case 16) with pre-existent renal insufficiency (creatinine 1000 μmol/L) recovered well but finally required permanent dialysis. Duplex examination showed patent renal arteries after the procedure, so it was likely that a combination of shock, contrast medium load, and the pre-existing renal status contributed to the deterioration. A third patient (case 15) developed a groin hematoma that did not require surgical intervention. All the other patients made an uneventfull recovery. The patients were fully mobilized between 1 and 5 days (mean 2.4), and they resumed a normal diet after a mean of 2.2 days (range 0-5). The hospital stay varied between 2 and 22 days (median 6).

During follow-up (range 3-44 months), three (19%) patients (cases 1, 2, 5) required stent-graft extensions because of distal endoleaks. This involved 1 Talent and 2 Vanguard devices, which had not been positioned to the level of the iliac bifurcation; additionally, the range of diameters of the devices was limited, which potentially compromised adequate wall contact. No late endoleaks have been

demonstrated. Two patients died from cardiac causes at 9 and 16 months respectively. All the other patients are doing well.

DISCUSSION

Open repair of acute AAAs requires general anesthesia and a laparotomy, which often induce additional hypotension in an already hypotensive patient. Open repair also has a major risk of iatrogenic injury during dissection. The urgent situation combined with these obvious risk factors make the procedure difficult for the surgeon and anesthetist and lead to a poor outcome for the patient.

Logically, both laparotomy and general anesthesia should be avoided. EVAR has been carried out under local anesthesia in the elective setting[20-22] and is technically possible in acute cases. Nevertheless, there are several impediments to this treatment option. First, an experienced endovascular team must be available 24 hours a day and a large range of devices covering all diameters and lengths must be at hand. Second, there has to be sufficient time to perform a CT scan for pre-operative measurements. Third, the patient has to be adequately stabilized and cooperative during the procedure.

In terms of treatment options, either a modular bifurcated graft or an aorto-uni-iliac stent-graft can be employed. Although sealing an aorto-uni-iliac stent-graft proximally is probably achieved more quickly, it requires additional procedures, such as adequate placement of an occluding stent-graft in the contra-lateral iliac artery and the mandatory femorofemoral prosthetic bypass graft. This necessitates two groin anastomoses in a questionable sterile situation, which implies an increased risk for infection. In addition, bilateral ischaemia will occur if the inflow device occludes due to later migration and/or kinking.

The modular bifurcated graft may take more time to complete the exclusion of the aneurysm, but patients are relatively stable in this hypotensive period, as shown by the Nottingham group.[23] We now use the modular Zenith Tri-Fab device, because it accommodates all aneurysms with suitable anatomy. Although it takes longer to deploy three parts to make one bifurcated graft, this stent-graft achieves the best physiological solution.

During the endograft procedure, intravenous fluid administration should be relatively modest in order to maintain a moderate but not too high blood pressure, since hypertension adds to the risk of free rupture. If the blood pressure is too low, a compliant balloon over a stiff guide wire can be inflated to achieve hemostasis and subsequent normotension. Although we did not need these balloons preprocedurally in our EVAR patients, we successfully applied the balloon in three patients before anesthesia and open repair.

The evolution from general to local anesthesia occurred gradually in our experience. Our first case (acute SAAA but no retroperitoneal hematoma on CT scan) was treated under general anesthesia, but the second case was similar, so we opted for local anestheis. The next patient was hypotensive from a ruptured aneurysm, but was already on the waiting list and a custom made graft was available, which facilitated our choice for local anesthesia. Two other patients with SAAA

preferred general anesthesia, but all subsequent cases were treated under local anesthesia.

All the patients undergoing EVAR under local anesthesia remained in a stable hypotensive condition with a blood pressure around 90/60 mmHg for the duration of the procedure. Patient movement during the procedure was not bothersome; they need to remain immobile only between the angiogram that establishes the position of the graft relative to the renal arteries and the deployment of the proximal stent. Our anesthetists carefully administer sedation or analgesia intravenously only if required.

At present, with an experience of over 250 elective EVAR cases, we have a 24-hours endovascular on-call team and sufficient stock of prostheses available at all times, so we hope to enroll more patients in this study in a shorter period of time. In addition, with these results in hand, it would be conceivable to select patients with less favourable anatomy, the first goal being to save the patients life. Long-term complications and endoleaks, which are not immediately life threatening, can be dealt with electively. In our initial series, only three patients required secondary procedures.

In conclusion, endovascular treatment of acute AAAs under local anesthesia is feasible and should be considered as a first choice in hemodynamically stable patients with suitable aneurysm anatomy. With local anesthesia, no further hypotension is induced during the procedure, and the patients tolerate the procedure well and recover quickly. Devices in all sizes need to be available, as does an experienced endovascular team. The use of a compliant balloon over a stiff guide wire before or during open repair needs further study.

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Chapter VI

ENDOVASCULAR TREATMENT OF ACUTE ABDOMINAL AORTIC ANEURYSM WITH A BIFURCATED STENTGRAFT

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INTRODUCTION

Open surgery for ruptured abdominal aortic aneurysm (AAA) still carries a high mortality, in a range between 35-70% among the patients who reach the hospital alive.[1-7] Despite advances in technology and critical care, this mortality rate has remained unchanged for the last two decades.[8]

The first report of emergency endovascular aneurysm repair (eEVAR) was published in 1994.[9] Several cohort studies followed with promising initial results.[10-17] Possible advantages of eEVAR are avoidance of both laparotomy and general anesthesia. General anesthesia has the disadvantage of deeper hypotension through loss of sympathetic nervous system compensation of hypovolemia.[18] Positioning the aortic clamp during urgent laparotomy can cause iatrogenic injury of the adjacent veins, including the caval vein and the left renal vein. Another key issue that has emerged with eEVAR is the principle of "hypotensive hemostasis". Many now believe that patients with a ruptured aneurysm should not be resuscitated aggressively, to prevent further rupture.

An obstacle to the widespread use of eEVAR is the need for an endovascular team to be available at all times. In addition, a subgroup of patients with ruptured aneurysm cannot tolerate any delay of treatment, such as caused by pre-operative CT scan needed for eEVAR.

This study reports a cohort of patients treated for an acute AAA in a single university hospital, and compares open repair and eEVAR mortality rates. In addition, suitability and application rate for eEVAR are assessed.

PATIENTS AND METHODS

- ***Evaluation of the patient***

  On arrival at the emergency department patients underwent immediate ultra-sound scanning to confirm the diagnosis of acute AAA, except in those cases in which the AAA was clearly palpable. All patients who were hemodynamically stable enough underwent immediate CT scanning. In cases of hemodynamic instability, the attending vascular surgeon had the option to send the patient for immediate open repair. Evaluation for eEVAR was performed by the endovascular team directly following the CT scan. Anatomical suitability for eEVAR was evaluated according to guidelines for elective EVAR including proximal neck length >1.5 cm with less than 60 degrees angulation, and access vessels large enough to accommodate the introducer systems. Several bifurcated modular devices were used including Vanguard® (Boston Scientific, Natick, MA, USA), Talent® (Medtronic World Medical, Sunrise, FL, USA), Zenith Tri-Fab® (William A. Cook Australia, Brisbane, Australia), and Excluder® (W.L. Gore and Associates, Flagstaff, AZ, USA) devices. In one case, an aorta-uni-iliacal (AUI) device was used (Zenith®, William A. Cook Australia, Brisbane, Australia).

- ***Operative technique and anesthesia***

  Every procedure was performed in an operating room using a mobile image

intensifier (OEC 9800, GE Medical Systems, Milwaukee, WI, USA) with digital substraction angiography and video output. Vascular access was obtained via bilateral surgical cut-down of the common femoral arteries. Local anesthesia was achieved with 1% lidocaine with epinephrine (maximum safe dose of 4 mg/kg). All patients were monitored non-invasively by the anesthetist. The goal was to maintain patients awake, cooperative, and able to control their breath. Intravenous (i.v.) sedation was used sparingly and only to achieve patient comfort. In case the patient suffered from pain, fentanyl, 50 – 150 µgs were given i.v. When indicated the patient was sedated with midazolam 0.05 – 0,2 mg/kg i.v. or with propofol 25 – 75 µg/kg/min i.v. In some cases remifentanil was administered in a dose of 0.1 µg/kg/min. To accurately deploy the stent-graft close to the renal arteries, intra-operative angiography was used, but only after the main delivery sheath had been advanced to the level of the first lumbar vertebra. As soon as possible, the empty sheath of the main device was removed (i.e. after full deployment and ballooning ipsilaterally), and purse strings, tightened with a Rummel's tourniquet, were used for hemostasis around the guide wire. This was left in place until the contra-lateral limb of the stent-graft was delivered and a completion angiogram obtained. After surgery, patients were cared for in the recovery room or transferred to the intensive care unit (ICU), depending on their condition.

- ***Study cohorts***

  Cohort I: peri-operative outcome and mortality

  All consecutive patients treated for an acute infra-renal AAA between January 1998 and August 2004 were included in this study. eEVAR was considered only if an endovascular team was present and a sufficient stock of devices available. From 2003 on, a policy was adopted of preferential eEVAR treatment for acute AAA.

  Primary endpoint in this study was in-hospital mortality. Secondary endpoints were peri-operative outcome measures including procedure time, intra-operative blood loss, need for blood transfusion (number of packed cells) during hospital stay, ICU length of stay, and hospital length of stay

  Cohort II: suitability and application rate

  To evaluate suitability and application rate of eEVAR, a cohort of patients presenting from January 2003 to August 2004 was studied. The following data were registered: number of patients reaching the hospital alive, number of patients not receiving treatment, number of patients evaluated for eEVAR, anatomical suitability, and number of patients treated by eEVAR.

- ***Definitions***

  Acute AAA was defined as any AAA requiring treatment within 24 hours. Differentiation was made between acute ruptured AAA (RAAA) and acute non-ruptured AAA (nRAAA). An acute AAA was only classified as RAAA in the presence of a retroperitoneal hematoma on the pre-operative CT scan in the eEVAR group, or at laparotomy in the open repair group. All other acute AAA were classified as acute nRAAA.

  Suitability for eEVAR was defined as the percentage of patients with an acute AAA evaluated by CT scan, who were anatomically candidates for eEVAR. Application

rate was defined as the percentage of patients treated with eEVAR out of the total treated group.

- *Statistics*
  Patient characteristics, operation data and peri-operative outcome data were recorded in a database with use of SPSS 10.0 data editor (Microsoft Corporation, USA). Statistical analysis was performed using Student t-test (normal distribution) and Mann-Whitney U test (skewed distributed) for continuous variables and Fisher's Exact test for categorical variables. Differences were considered significant with $p< 0.05$.

RESULTS

Cohort I: peri-operative outcome and mortality

A total of 262 patients with an acute AAA were admitted to the emergency department. Nine (3%) patients were not treated because of old age combined with co-morbidity, leaving 253 patients in the study group. Patient characteristics of the eEVAR and open treated groups are summarised in Table 1. Differences between both groups included older age in the eEVAR group, and more RAAA in the open group.

The hemodynamic condition of the eEVAR patients is summarised in Table 2. The following devices were used in the eEVAR group: 30 Zenith Tri-Fab®, one Zenith AUI®, three Excluder®, three Vanguard®, and two Talent® devices. Local anesthesia was used in 33 (83%) patients. Four (10%) patients were treated under general anesthesia and three (7%) patients required conversion from local to general anesthesia.

For treated patients, overall in-hospital mortality was 69/253 (27%). Mortality was significantly lower in the eEVAR group compared to the open group (eEVAR 13% vs. open 30%, p=0.021). When only RAAAs were considered, there was no difference in mortality between open repair and eEVAR (Table 3). Only a minority of patients presented with nRAAA and no difference between the treatment groups was evident (Table 3). Procedure time, blood loss, transfusion need, ICU length of stay, and hospital length of stay were all significantly lower in the eEVAR group ($p<0.001$) (Table 1).

There were three intra-operative technical problems requiring open surgery. One patient was converted to open repair because of insufficient access. This became evident after cut-down of the common femoral arteries and a try-out with a 12 French sheath. Immediately open repair was undertaken. A second patient with an aorto-iliac aneurysm including both common iliac arteries underwent a laparotomy to ligate both hypogastric arteries after eEVAR. Finally, a third patient underwent a laparotomy at the end of the procedure because of abdominal compartment syndrome, a very large retroperitoneal hematoma was evacuated.

Among the 40 patients who underwent eEVAR, five (13%) patients died. Two of them were patients who needed additional open surgery as mentioned above. The patient who needed conversion to open repair developed ischaemic colitis and died

Table 1. Characteristics and peri-operative outcome of the open and eEVAR group

	OPEN n=213	eEVAR n=40	p
Sex			
Male	185 (87%)	37 (92%)	0.434
Female	28 (13%)	3 (8%)	
Age (years)			
Median	71	75	0.042
Range	48-87	54-87	
Ruptured or Non-ruptured			
Ruptured	172 (81%)	25 (62%)	0.021
Non-ruptured	41 (19%)	15 (38%)	
Procedure time (min)			
Median	180	110	<0.001
Range	30-375	55-240	
Bloodloss (ml)			
Median	3500	200	< 0.001
Range	200-26000	50-2800	
Transfusion need (pc)			
Median	6	0	< 0.001
Range	0-65	0-13	
Hospital length of stay (days)			
Median	12	5	< 0.001
Range	1-102	1-22	
ICU stay (hours)			
Median	48	0	< 0.001
Range	0-2328	0-336	

Open, open repair; eEVAR, emergency endovascular aneurysm repair; pc, units of packed cells; ICU, intensive care unit.

Table 2. Systolic bloodpressure of the eEVAR group on arrival at the emergency department

Systolic BP (mm Hg)	RAAA	Mortality	nRAAA	Mortality
< 70	7	4	0	0
70 – 100	15	0	0	0
> 100	3	1	15	0

BP, bloodpressure; RAAA, ruptured abdominal aortic aneurysm; nRAAA, non-ruptured abdominal aortic aneurysm

12 days later of multiple organ failure. An 83-year-old patient needing laparotomy to ligate both hypogastric arteries died at the end of the procedure from hypovolemic shock. A third patient died 3 days after successful aneurysm exclusion due to cardiac failure. A fourth patient underwent acute aorto-uni-iliac stent-grafting, followed by femorofemoral cross over, requiring conversion from local to general anesthesia. He died 12 days post-operatively due to respiratory insufficiency.

The fifth patient in the eEVAR group died 1 hour after the procedure, most likely due to hypovolemic shock following a lengthy procedure.

Cohort II: suitability and application rate

Between January 2003 and August 2004, 59 patients were admitted to our hospital with an acute AAA. (Fig. 1). Three patients were not treated due to old age and co-morbidity. The remaining 56 (95%) patients were treated. From this group, 44 (79%) patients were evaluated for eEVAR by CT scan. Twelve (21%) patients were not evaluated for eEVAR, because they were too shocked (n=8), or because no endovascular team was available (n=4). Of the 44 evaluated patients, 28 (64%) patients were considered unsuitable for eEVAR for the reasons described in Table 4. Sixteen patients (suitability 16/44 or 36%) were considered anatomically suitable for eEVAR. One of these 16 patients received open repair because of suspicion of a mycotic aneurysm. This diagnosis was based on clinical presentation, infectious parameters, CT scan findings, and a positive blood culture with *haemophilus influenzae.* Fifteen patients were treated by eEVAR (application rate 15/56 or 27%).

Table 3. Mortality of acute ruptured and acute non-ruptured AAA patients

	Open		EVAR		p
	n	Mortality	n	Mortality	
RAAA	172	57 (33%)	25	5 (20%)	0.250
nRAAA	41	7 (17%)	15	0	0.171
Total	213	64 (30%)	40	5 (13%)	0.021

RAAA, ruptured abdominal aortic aneurysm; nRAAA, non-ruptured abdominal aortic aneurysm

■ DISCUSSION

The overall mortality in this study (27%) compares well with published results, particularly if we take into account that 95% of the patients with an acute AAA was treated.[1-8] The eEVAR mortality rate (13%) was in accord with previous studies, reporting mortality rates ranging from 9 to 19%.[11-16] Mortality of the nRAAA subgroup treated by open repair (17%) was high, but similar to other reports, with mortality rates between 9 to 18%.[19-22] The deceased patients with a nRAAA (n = 7) had extensive co-morbidity, and three were more than 80 years old. In addition, the open group was classified strictly: only a positive report of a retroperitoneal hematoma or free rupture was accepted as RAAA.

It is difficult to attribute a positive effect of eEVAR on the overall mortality, because eEVAR was only used in a small proportion of the entire cohort. The open and eEVAR group are not comparable due to a difference in ratio nRAAA/RAAA. In addition, there is bias in favour of the eEVAR group due to anatomical, and hemodynamic selection. Several patients were not evaluated due to hemodynamic instability, and treated by open repair. However, four out of the five patients who

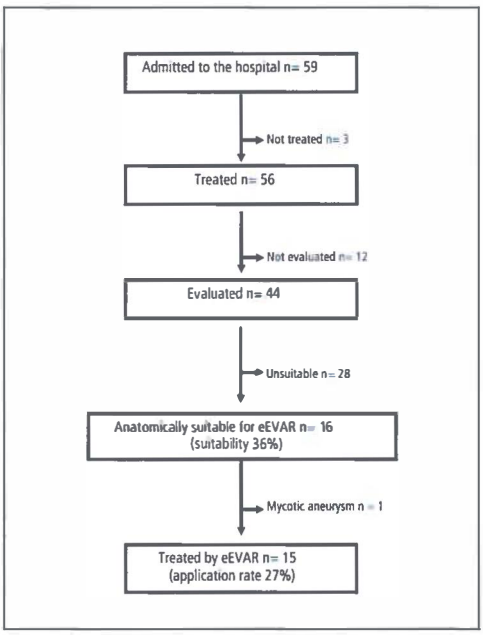

Figure 1. Patient inclusion from January 2003 to Augustus 2004

died after eEVAR, were hemodynamically unstable with a blood pressure of <70 mmHg on arrival, as shown in Table 2. Nevertheless, the results of eEVAR in the nRAAA group are promising and the results in the RAAA group acceptable.

There are lessons to be learned from the eEVAR group. The results of eEVAR include one patient who died after conversion to an open repair. At the beginning of the endovascular procedure, access proved impossible. Open repair was carried out, with an estimated delay of about 30 minutes. The patient died 12 days later from multiple organ failure. This mortality was allocated to the eEVAR group, based on the intention-to-treat principle. In a second patient, with an aorto-iliac aneurysm, aged 83 and in a poor hemodynamic condition, eEVAR was attempted, but tha patient died at the end of the procedure. In retrospect, this patient with a large bilateral aorto-iliac aneurysm was not a good candidate. Currently, this type of aneurysm is excluded from eEVAR in unstable patients, because quick sealing is not possible, and additional techniques are required to seal the internal iliac artery back flow. A bell-bottom technique is a good option, but will treat common iliac artery aneurysms only up to 22 mm in diameter.

A clear advantage of eEVAR over open repair was demonstrated in terms of procedure time, blood loss, blood transfusion requirements, ICU length of stay, and length of hospital stay. These advantages are in accord with the literature on elective EVAR and they will contribute to cost-effectiveness of eEVAR.[23,24]

Logistics do play an important role in the treatment of acute AAA. In our institution, we operate a warning system through the ambulance services. This triggers a series of actions: CT scan and operating theatre are made available before arrival of the patient, and a team consisting of a vascular surgeon, a radiologist, and an anesthetist are present at the emergency department before arrival of the patient. In addition, experienced theatre nurses and radiology technicians are present day and night. Nevertheless, it is difficult to have an experienced endovascular team available at all times.

The cut-off point of January 2003 for the suitability and application rate assessment was chosen, because it marks our policy shift towards preferential treatment of acute AAA by eEVAR. Previous to this time, we did not have sufficient stock of devices available at all times, particularly on the two occasions when a stocked device was withdrawn from the market. Although we used and still use different devices in the elective setting, it is impossible to have them all on stock.

Evaluation for eEVAR occurred in 79% of the patients with an acute AAA. Twenty-one percent of the patients were not evaluated: eight (14%) patients because of hemodynamic instability, and four (7%) patients because an endovascular team was not available immediately.
Studies of untreated RAAA patients showed that most patients (87%) admitted to the hospital, died only after more than 2 hours. The authors concluded that most patients with a RAAA are stable enough to undergo evaluation for eEVAR.[19,20] As in our study, the literature reports that 85-90% of patients with an acute AAA are stable enough to allow delay of treatment and warrant evaluation by CT scan. Enhancing hemodynamic stability by inserting and inflating an aortic balloon in the remaining group of patients, who are too unstable, is another possibility, but a disadvantage is the worse quality of the intra-operative angiography due to a lack of flow. The logistic problem regarding the non-availability of an endovascular team could be solved with increasing experience.
In our study, we found an anatomical suitability of 36%. This is in accord with the literature on CT scan studies, reporting anatomical suitability between 20 and 45%.[25-27] The application rate was low (27%). Recent clinical studies have reported an application rate between 20 and 80%.[11-16,28] Taking the suitability studies into account, this wide range in application rate might be explained by a more liberal application of inclusion criteria, or by pre-selection due to a different referral pattern by surrounding hospitals. With regard to the inclusion criteria, one can argue whether a 5-15 mm neck should be a contra-indication for eEVAR. In the elective setting, initial results of stent-grafting in such 5-15 mm necks have been positive.[29] Obviously, long term results have to be awaited to change the inclusion criteria in the elective setting. In the acute setting, the goal is to save the patients' life and, therefore, a shorter neck might be acceptable. In our hospital, we have started a prospective trial of eEVAR, in which we accept some shorter necks. With regard to pre-selection, we have not yet adopted a policy of accepting stable acute AAA from other hospitals. Our policy is that patients with an acute AAA should not be transferred unless there is no treatment option in the local hospital. In our series, seven of the 59 patients with an acute AAA were referred from other hospitals, because urgent treatment was technically impossible in the local hospital due to the non-availability of a vascular surgeon, or an intensive care unit facility. Only two out of these seven patients were treated with eEVAR (one survived, one died).

Table 4. Contra-indications to eEVAR

Feature	Number of patients	
Short neck (mm)	n=13	(46%)
< 5	n=8	
5-10	n=4	
10-15	n=1	
Aorto-iliac aneurysm	n=8	(29%)
No access	n=1	(4%)
Combination	n=6	(21%)
Total	n=28	

CONCLUSION

Overall mortality of acute AAA was low (27%). Mortality in the eEVAR group was lower than in the open group, but eEVAR was only used in a small proportion of selected patients. eEVAR was associated with a shorter procedure time, a shorter hospital and intensive care unit length of stay, and lower blood loss and transfusion requirements. Suitability and application rate of eEVAR for acute AAA were 36% and 27%, respectively.

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Chapter VII

ENDOVASCULAR AORTIC ANEURYSM REPAIR WITH FENESTRATED STENT-GRAFTS TO TREAT SHORT-NECK INFRARENAL AORTIC ANEURYSMS: SHORT-TERM RESULTS.

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INTRODUCTION

It is now more than 10 years since Parodi reported the first endovascular repair of aortic abdominal aneurysms (EVAR), initially with tube-grafts and later with bifurcated grafts.[1] Since then, many patients have been treated with different endovascular devices.[2-6] For each of these devices, there are comparable anatomical requirements for a successful EVAR. One of the necessary anatomical features is a good proximal neck, i.e. a non-tapered cylindrical portion of at least 15 mm below the renal arteries.[7-9] Several devices now present with transrenal/suprarenal fixation, to enhance the stability in the proximal neck.[10-16] Nevertheless, in general, patients with proximal necks shorter than 15 mm are regarded as unsuitable for endovascular repair. An additional reason for concern is proximal neck dilatation after EVAR.[17-23]

These problems can be solved by using a customized stent-graft design including fenestrations for the aortic side branches above such a short neck (i.e. the renal arteries and the superior mesenteric artery). It enables the first sealing portion of the stent-graft to be positioned in a more stable part of the aorta with the customized fenestrations at the exact origin of the targeted vessels. This approach makes it possible to treat patients with short necks and perhaps patients with some juxtarenal aneurysms.[24-26]

This paper reports the early experience from a European centre with a large endovascular experience, and discusses the possible benefits of this technique.

PATIENTS AND METHODS

Between November 2001 and April 2003, 18 patients with an AAA greater than 55 mm in diameter underwent EVAR with a fenestrated graft. All patients had proximal necks unsuitable for standard EVAR (Table 1). All patients had significant co-morbidity or a hostile abdomen that precluded open abdominal repair. Six patients had cardiac, five patients cardiac and pulmonary, and three patients pulmonary contra-indications. Two patients had hostile abdomens, one after an open cysto-prostatectomy and radiotherapy and one with a productive aorto-enteric fistulae. Finally, three patients (one already mentioned with a hostile abdomen) had a type I endoleak after previous stent-grafting with a neck that was too short. Informed consent was obtained from all patients.

- ***Stent-graft configuration***

Detailed evaluation of the proximal neck was obtained by spiral CT with axial and perpendicular reconstructions. A calibrated angiogram was also performed. The stent-graft used was a composite endoluminal prosthesis based on the Zenith system (William A. Cook Australia Pty. Ltd., Brisbane, Australia), which has a self-expanding modular design with an uncovered Gianturco Z-stent (William Cook Europe, Bjaeverskov, Denmark) for proximal fixation in the standard configuration. The proximal anchor stent, which has multiple spikes at its upper end to enhance fixation, is designed for suprarenal implantation.

Table 1: Patient and fenestrated stent-graft characteristics with targeted vessels and procedural outcome.

	Age	Sex	ASA	AAA size* (mm)	Neck lenght (mm)	Anesthesia (GA;EA;LA)	RRA	LRA	Acc.	SMA	Number of side branches Perf/Targ	Endo-leak (type)
1	71	M	4	62	6	EA	1	1	0	0	2/2	
2	73	F	3	55	10	EA	1	1	0	0	2/2	
3	76	M	3	57	8	EA	1	1	1	1	3/4	
4	77	M	3	60	8	GA	1	1	0	1	3/3	
5	73	M	3	Type I	4	GA	1	1	0	1	3/3	
6	60	M	3	55	7	EA	1	1	0	1	3/3	Type II
7	75	M	3	Type I	10	EA	1	0	0	0	1/1	Type I → Type II
8	79	M	3	55	9	EA	1	1	0	0	2/2	Type II
9	66	M	2	55	6	EA	1	1	0	1	3/3	
10	66	M	3	Type I	10	LA	1	1	0	0	2/2	
11	78	M	3	57	10	EA	1	1	0	0	2/2	
12	70	M	3	57	6	EA	1	1	0	0	2/2	
13	77	M	3	58	6	EA	1	1	0	1	3/3	
14	81	M	2	58	6	LA	1	1	0	1	3/3	
15	62	M	3	58	8	LA	1	1	0	0	2/2	
16	85	F	2	60	8	EA	1	1	0	1	3/3	
17	78	M	3	70	10	EA	1	1	0	1	3/3	
18	83	M	3	62	8	EA	1	1	0	1	3/3	

M, male; F, female; ASA, American Society of Anesthesiologists Physical Classification; AAA, abdominal aortic aneurysm; * diameter of aneurysm or type I endoleak after EVAR; GA, general anesthesia; EA, epidural anesthesia; LA, local anesthesia; RRA, right renal artery; LRA, left renal artery; Acc. RA, accessory renal artery; SMA, superior mesenteric artery; Perf, perfused; Targ, targeted;

There was one major modification with regard to the Australian study.[25] In contrast to the previous bifurcated two piece fenestrated system, we used a composite system composed of a tube in which a bifurcated device is to be positioned (Fig. 1). A contra-lateral limb completes the three-part configuration. The tube graft was also fitted with diameter reducing ties to allow only partial deployment prior to catheterisation of the side branches and final orientation of the stent-graft.
Customization of the stent-grafts was based on each individual configuration. Three types of fenestrations were possible: scallops, large and small fenestrations (Fig. 2). Each fenestration was marked by three (scallop) or four (small or large fenestration) radiopaque markers to enable accurate alignment. Each tube graft was fitted with anterior and posterior markers to facilitate orientation during insertion and deployment.

- ***Implantation technique***
  Patients were treated under general, epidural or local anesthesia according to the judgement of anesthetist and surgeon, in concert with the patient. Two patients were treated under general anesthesia, 13 under epidural anesthesia, and three under local anesthesia (Table 1). Patients were prehydrated with IV solution 12

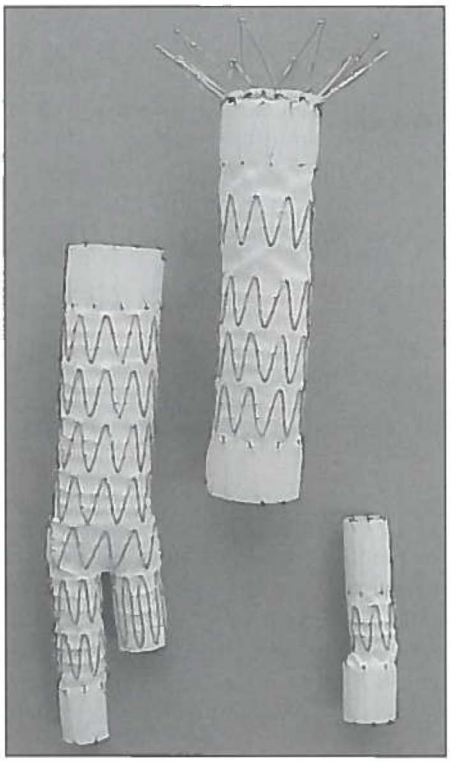


Figure 1. The Cook Zenith composite 3-part system: fenestrated tube, bifurcated graft, and contra-lateral limb.

hours before the procedure and renal output was carefully monitored. All the procedures were performed in an operating theatre with the use of a mobile C-arm (OEC 9800, General Electric Medical Systems, Salt Lake City, Utah, USA).

The technique used was very similar to the set-up of our Australian colleagues in Perth and Adelaide24-26. The complete deployment of the stent-graft was always carried out after catheterisation of the side branches and after adjusting the position by means of inflated balloons. Stenting of small fenestrations was routinely performed. The idea of stenting being to secure the orifice of the side branch but also to accurately appose the fenestration with the ostium of that side branch. After completion of the procedure with the bifurcated system and the contra-lateral limb, a completion angiography was carried out to confirm vessel patency and complete exclusion of the aneurysm. If necessary multiplanar angiography was performed.

- ***Follow-up***
  All patients were followed-up with abdominal X-rays, duplex and CT scan at 6 weeks, 6 months and 1 year. In addition, their renal function and blood pressure were monitored.

■ RESULTS

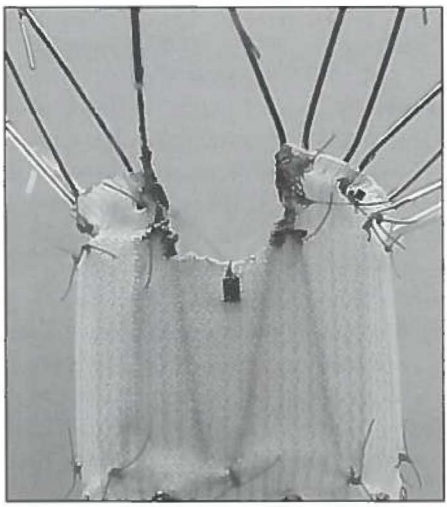
All endovascular procedures were successful. There were no conversions to open surgery. Completion angiography showed complete exclusion of the aneurysm in 15/18 patients (Table 1). There were three endoleaks: one possible small type I endoleak and two type II endoleaks. At the end of the procedure, 45/46 targeted side branches were clearly patent and one accessory renal artery was occluded (patient number 3). In total, we used two large fenestrations, 20 small fenestrations and 24 scallops for 10 superior mesenteric arteries, 35 renal arteries and one accessory renal artery. Additional stent placement was carried out in 18 of the 20 small fenestrations. The two small fenestrations not stented were for the main renal

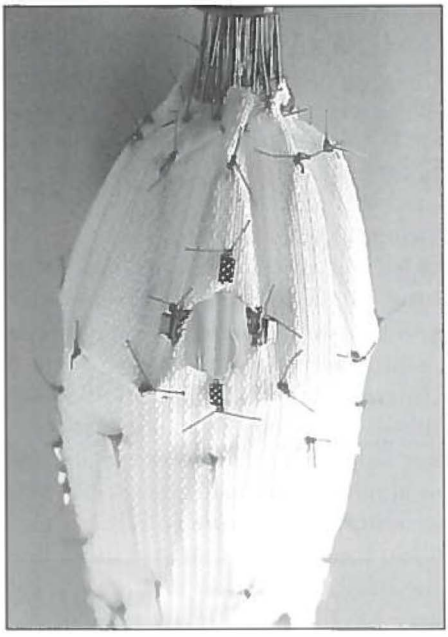
artery and an accessory renal artery, both on the left side in patient number 3. Here, the final angiogram showed a good perfusion of the main renal artery, but an occlusion of the accessory renal artery. We met with three types of technical problems in eight different patients. In three patients, the sheaths leaked continuously due to the simultaneous catheterisation with different wires, catheters and balloons, causing additional blood loss (1000, 1100 and 1700 ml, respectively). In three patients, catheterisation of the right renal artery proved difficult and time consuming. In two patients, the iliac access was very difficult. Each of these technical problems was eventually solved.

- ***Operative details***
  The mean duration of the procedure was 166 minutes (range 110-270) and the mean blood loss was 450 ml (range 100-1700). The mean amount of contrast used was 170 ml (range 80-240). The mean radiation time was 16 min (range 9-28), using pulse fluoroscopy whenever possible.

- ***Mortality and morbidity***
  There was no surgical mortality. There were complications in six patients. Patient number 13 suffered from cardiac decompensation, possibly related to a minor myocardial infarction, with subsequent pneumonia. Patient number 17 developed atrial fibrillation, which was treated with medication. Three patients (1, 5 and 7) suffered from urinary complications (two urinary retentions and one urinary tract infection). Patient number 7 also suffered from a retroperitoneal hematoma, which was treated conservatively. In patient number 3, we noted moderate perfusion of the left upper pole and bad perfusion of the left lower pole of the kidney after occlusion of the accessory renal artery. A spiral CT scan showed an excluded aneurysm, with an occluded accessory renal artery and a severe stenosis of the left renal artery. We were unable to catheterise the tight stenosis and eventually lost the left kidney, although the completion angiogram at the initial operation showed a perfect result. Hospitalisation varied from three to 12 days with a mean of 6.4 days, including the pre-operative admission day. Two patients went to the ICU: one as a precaution for one day, and patient number 13 with the cardiac complications.

- ***Follow-up***
  The mean follow-up is 9.4 months (range 1-18). Except for the one problem already mentioned, there were no other patency problems with the targeted vessels. All vessels appeared fully patent on spiral CT scan (routine endovascular follow-up at 6 and 12 months post-operatively). Renal function was normal in all patients and none developed hypertension.
  The three suspected endoleaks were followed closely. In patient number 8, the type II endoleak from an open inferior mesenteric artery persisted and was successfully treated by supraselective embolisation. In patient number 6 the type II endoleak from lumbar arteries disappeared, with the aneurysm shrinking. Therefore no treatment was required. In patient number 7, we suspected a small pertinent type I endoleak but spiral CT scan and subsequent angiogram suggested a type II endoleak caused by lumbar arteries. This endoleak persisted and the aneurysm did not





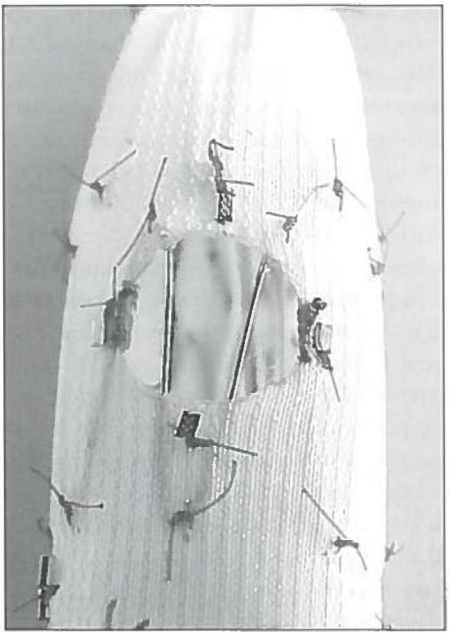


Figure 2. Different types of fenestrations: scallop, small fenestration, and large fenestration.

shrink. Finally, we decided to do a laparotomy for final diagnosis and treatment. After careful opening of the sac (without clamping) and removal of the thrombus, we discovered four patent lumbar arteries, which were all oversewn. The aneurysmal sac was then wrapped around the stent-graft. The patient recovered well from the laparotomy.

Patient number 3, who lost his left kidney, died after 8 months due to metastatic adenocarcinoma (no primary tumour found). All the other patients are doing well.

DISCUSSION

The technique originally devised by the combined efforts of Cook Australia (David Hartley) and the endovascular teams of Perth (Michael Lawrence-Brown) and Adelaide (John Anderson) aimed at dealing with AAAs with proximal necks shorter than 15 mm in length.[25,26] By customizing fenestrations and/or scallops for the renal arteries and, if required, the superior mesenteric artery, the proximal covered stent can be positioned in a more proximal and, therefore, straighter part of the aorta. It seems logical that this will improve the stent-graft's stability. However, the technique is complex, since it requires simultaneous catheterisation, ballooning and sometimes stenting of the targeted vessels. The procedure is significantly longer than a standard EVAR procedure (166 min vs. 110 min in our hospital). This makes general anesthesia or IV sedation in addition to epidural or local anesthesia often necessary. We also used more contrast medium compared to the standard EVAR procedure (170 ml vs. 100 ml). Until now our only precaution to avoid nephrotoxicity was to prehydrate the patients overnight before the procedure. An additional measure is possibly the use of CO2 angiography for part of these procedures. Radiation times appear low with a mean of 16 min (range 5-28). However, one has to take in account that we used pulse fluoroscopy whenever possible and accepted the sometimes lower quality of the image. The pulse fluoroscopy reduced the mean radiation time in standard EVAR procedures from 29 to 4 min. The radiation time during fenestrated stent-grafting is significantly higher than standard EVAR procedures (16 min vs. 4 min).

With regard to sealing of the aneurysm and patency of the targeted side branches, accurate positioning is mandatory. We decided not to stent scallops, nor large fenestrations. In our view scallops should be used for the upper targeted vessels like the superior mesenteric artery or the higher of two asymmetric renal arteries. The goal here is to maintain patency. Sealing is not the issue. This means that the fenestrations/scallops can be made larger to ensure good patency. In addition, stenting of large fenestrations can be very difficult due to the fact that they present with struts crossing the fenestration. Smaller fenestrations are reserved for the crucial lower renal vessels but inaccurate positioning is not easily detectable with angiography. We prefer to stent every small fenestration to ensure correct position at the orifice of the artery and to give additional fixation of the stent-graft. In one case (patient number 3) we did not stent the small fenestration to the left renal artery. Having stented the right renal artery, we tried to stent the left side but lost access and abandoned the stenting in view of a perfect angiographic image. Nevertheless, after one month, the renal artery orifice became severely stenosed. Attempts to recanalise and stent the artery failed and the left kidney was lost. We now stent every small fenestration.

The stent-graft we used is a three-piece device. Therefore there is increased risk of type III endoleaks due to disconnection. We regard a long overlap zone of three covered stents between the proximal tube and the bifurcated second piece mandatory, as we are aware of two non-published disconnections between the two upper parts. The contra-lateral stump can be positioned on the aortic bifurcation to add to the stability of the remaining connection with the contra-lateral limb.

This procedure, which we carried out in high risk patients, is a lengthy and difficult

one. This probably contributed to the morbidity: two cardiac and three urinary complications as well as a retroperitoneal hematoma, probably due to anti-coagulation therapy through-out the whole procedure. This has to be taken in account when one considers the different options (i.e., open vs. fenestrated) for any patient.

In conclusion, as previously shown shown by John Anderson,25 this technique is feasible but it requires great experience in endovascular stent-grafting and renal stenting due to its complexity. In our view, it should be reserved for patients who are at higher risk from open repair and in whom a normal endovascular procedure is precluded because of a short proximal neck.[27-29] However, ths stability of this stent-graft system and the patency of the stented fenestrations remains to be proven in the mid- and long-term.

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Chapter VIII

FENESTRATED AND BRANCHED ENDOVASCULAR TECHNIQUES FOR THORACO-ABDOMINAL ANEURYSM REPAIR

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Since the introduction of endovascular aneurysm repair (EVAR) by Parodi in 1991, the technique has been embraced as a viable alternative to open repair.[1] Up to now, two prospective randomized trials have demonstrated immediate benefits compared to open surgery.[2,3] Critics rightfully argue that the mid- and long-term results may be inferior to open surgery due to a larger number of late complications, though most of these complications can be treated again by endovascular means.[4,5] Other advantages of endovascular repair both in abdominal and thoracic EVAR include the use of regional and local anesthetics.[6-9] Another milestone was achieved with the introduction of emergency EVAR for ruptured aneurysms.[10-14] Still, a major limitation of EVAR is the necessity of a suitable proximal and distal portion of normal aorta to serve as a sealing zone for the stent-graft. Vital side branches, such as the celiac axis, the superior mesenteric artery, and both renal arteries cannot be sacrificed without risk. The proposed solution to this problem is the customization of fenestrated and branched stent-grafts to incorporate the vital side branches.
This paper reviews the published literature on facilitated endovascular techniques for the exclusion of thoraco-abdominal aneurysms, including fenestrated and branched grafts. Additionally, a new classification for these procedures is suggested. Nevertheless, one has to take into account that all techniques are linked and hybrid grafts and techniques have emerged. The only well-elaborated technique at this moment is abdominal fenestrated stent-grafting, which has become more widely available and now warrants a real option for (high-risk) patients with a short-necked abdominal aortic aneurysm. This review will elucidate this specific category extensively. Branched stent-grafting, in contrast, must be regarded as highly experimental. These stents are not widely available yet and have been used only in a few well-selected patients by a small number of centers.

CLASSIFICATION OF PROCEDURES WITH FENESTRATED AND BRANCHED STENT-GRAFTS

Fenestrated and branched grafts share a common goal, i.e. the exclusion of flow towards the aneurysm with maintenance of flow to vital aortic branches. Fenestrated grafts are dedicated to treat aneurysms with a neck too short for standard EVAR. The fenestrations accommodate vital side branches, but apposition with the wall is necessary to create a seal. Branched grafts do have incorporated side branches. Their use is for those aneurysms with no neck at all. The gap between the side branch and the target vessel can be overcome with a bridging stent-graft or a covered stent. Hybrid grafts or techniques can also be used. Moreover, a fenestrated graft in which the fenestration is provided with a covered stent instead of a bare stent becomes in fact a branched graft. Based on the targeted side branches and the anatomical placement of the stent-graft, it is possible to classify all fenestrated and branched procedures as follows:

- Abdominal fenestrated: stent-grafts with incorporated fenestrations and/or scallops to target short neck infrarenal abdominal aneurysms. The goal is to incorporate renal arteries and, if necessary, the superior mesenteric artery.

Fenestrations or scallops can be fitted with bare stents in order to create additional fixation and to maintain ideal apposition.

- Abdominal branched: stent-grafts with incorporated fenestrations and/or scallops or branches to target juxta- or suprarenal abdominal aneurysms. The goal is to incorporate renal arteries and, if necessary, the superior mesenteric artery and the celiac trunk. The fenestrations or scallops and the branches are fitted with covered stents to provide full seal and apposition.
- Thoraco-abdominal fenestrated: stent-grafts with a distal large scallop or fenestration to accommodate the celiac trunk and the superior mesenteric artery. The goal is to treat thoraco-abdominal aneurysms (TAAA's) with a short distal neck with regard to the celiac trunk.
- Thoraco-abdominal branched: stent-grafts with branches for celiac trunk and/or superior mesenteric artery and/or renal arteries. The goal is to treat type III or type IV TAAA's according to the Crawford classification.
- Thoracic fenestrated: stent-grafts with a large proximal scallop or fenestration to incorporate the subclavian artery or the left carotid artery. The goal is to treat thoracic aneurysms with a short proximal neck.
- Thoracic branched: stent-grafts with fenestrations or branches in their proximal end to incorporate the subclavian artery and/or the left carotid artery and/or the innominate artery. The goal is to treat thoracic arch aneurysms with no neck with respect to the above mentioned arteries.

- ***Abdominal fenestrated***

Literature review At this moment, the technique is gaining interest rapidly with over 400 cases performed worldwide. In 1996, Park et al. reported the first two case reports.[15] In the first patient with occluded celiac trunk and superior mesenteric artery, a tube graft with a fenestration to preserve the inferior mesenteric artery was used to treat an anastomotic aneurysm. In the second patient, a graft with a single fenestration for a low right renal artery was used to exclude an abdominal aortic aneurysm. Three years later, an experiment in two dogs with a Dacron covered stent and one fenestration to preserve flow to the right renal artery was published by Browne et al.[16] Human case reports followed, published by Faruqi et al. in the same year, and by Kinney et al. in 2000.[17,18] In the first report, a single renal artery was preserved by a fenestrated graft. In the second report, a tube graft with a large diamond shaped fenestration positioned anteriorly was used successfully to exclude a mycotic paravisceral aneurysm. The fenestration included both the superior mesenteric artery and the celiac trunk. The first human cohort study was reported in 2001 by Anderson et al.[19] They reported a series of 13 patients in which 33 renal and superior mesenteric arteries were targeted, with a 100% procedural success rate and nil 30-day mortality. Follow-up between three and 24 months revealed one occlusion of a renal artery with subsequent loss of the kidney. Stanley et al. reported a case treated with the same technique.[20] Larger cohort studies were published in 2004. Greenberg et al. reported a total of 22 patients with 58 targeted visceral vessels.[21] There was no mortality and only one occlusion and two stenoses in targeted vessels in a six months follow-up period. The 30-day endoleak rate was 4.5%. Greenberg et al. also published an extended series of 32 patients with a

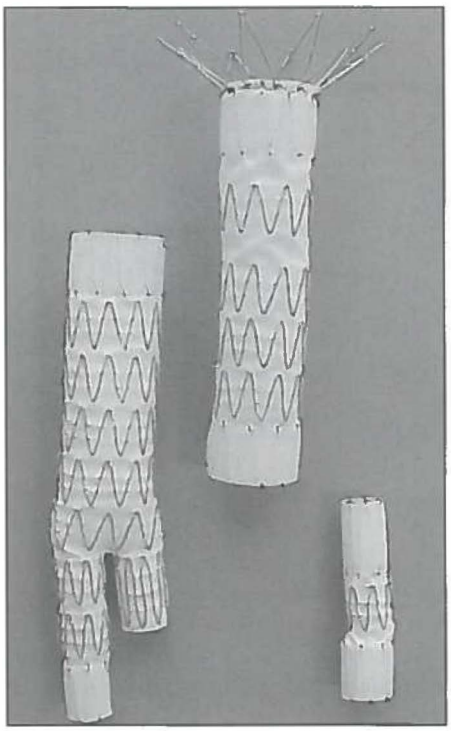


Figure 1. Composite three-part Zenith stent-graft used for customization of fenestrations and scallops.

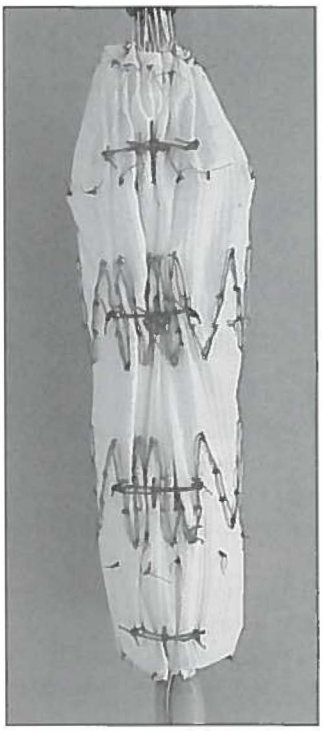


Figure 2. Diameter reducing ties, with the purpose to constrain the graft to 60-70% of its intended diameter, allowing repositioning and final orientation.

mortality of one patient (3%) and two late renal artery occlusions.[22] We reported a series of 18 patients with a procedural success of 45 out of 46 targeted vessels with the loss of only one accessory renal artery. During mean follow-up of 9.4 months one additional targeted vessel occluded, causing the loss of one kidney. There were no proximal type I endoleaks.[23]

Pooled results of the published experience demonstrate that this surgery may be accomplished with 99 % (95% Confidence Interval [CI] 92 - 99 %) technical success, 30-day mortality 1.5 % (95% CI 0.4 - 8%), and acute loss of visceral arteries of 1.5 % (95% CI 0.4 - 8%). At an average follow up of 11 ± 2 months (1 to 24), complications include type I proximal endoleaks 3% (95% CI 0.4 - 10%), occlusion of renal arteries 6% (95% CI 1.7 – 15%), reinterventions 12% (95% CI 5 - 22 %), and no renal failure requiring dialysis. Long-term follow up for this type of repairs remains limited but durability appears to be promising.

Technique The stent-graft now used is a composite endoluminal prosthesis based on the Zenith system (William A. Cook Australia Pty. Ltd., Brisbane, Australia), which has a self-expanding modular design with an uncovered Gianturco Z-stent (William Cook Europe, Bjaeverskov, Denmark) for proximal fixation in the standard



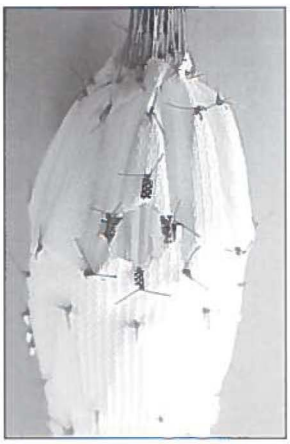


Figure 3a. A scallop in the top of the stent-graft.
Figure 3b. A large fenestration (metal struts crossing).
Figure 3c. A small fenestration (no metal struts across).

configuration (figure 1). The proximal part of the graft is fitted with diameter reducing ties to allow only partial deployment prior to catheterization of the side branches and final orientation of the stent-graft (figure 2). Customization of the stent-grafts is based on each individual anatomical configuration. Three types of fenestrations are possible: scallops, large and small fenestrations (figure 3a, 3b, 3c). Each fenestration is marked by three (scallop) or four (small or large fenestration) radiopaque markers to enable accurate alignment. Each tube graft is fitted with anterior and posterior markers to facilitate orientation during insertion and deployment. Complete deployment of the stent-graft has to be carried out after catheterization of the side branches and after adjusting the position by means of inflated balloons or guiding sheaths. Stenting of small fenestrations has been applied in most cases (figure 4). The idea of stenting is to secure the orifice of the side branch but also to match the fenestration with the ostium of that side branch.

Evolution A major advancement of the technique was the decision to move towards the so-called composite system instead of a bifurcated system. The goal behind this was to make catheterization of the fenestrated tube and the side branches easier and to position the second bifurcated part as close as possible to the aortic bifurcation. The credit for this system has to go to W. Stelter from Frankfurt, who also advocates this composite system for non-fenestrated cases. Another improvement includes the stenting of both small fenestrations and scallops, to assure full apposition of the fenestrations to the targeted vessel. This policy was introduced because most of the late occlusions occurred in non-stented small fenestrations and scallops. At this moment, we are moving towards reinforced fenestrations and scallops (figure 5). This reinforcement holds the fenestration/scallop open for catheterization in the middle stages of deployment when the body of the stent-graft is still in a partially compressed state.

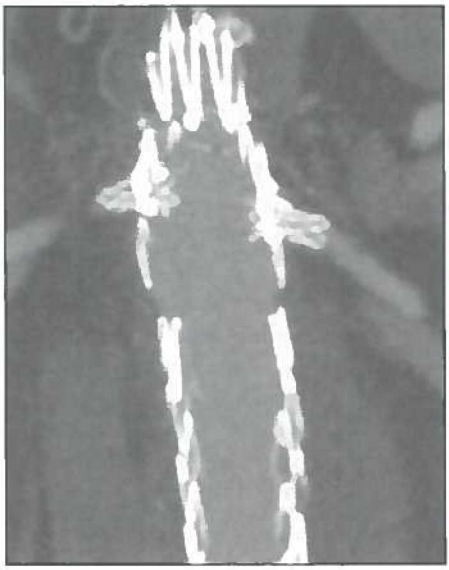


Figure 4. Stents in small fenestrations to maintain fixation and apposition.

Figure 5. A reinforced small fenestration.

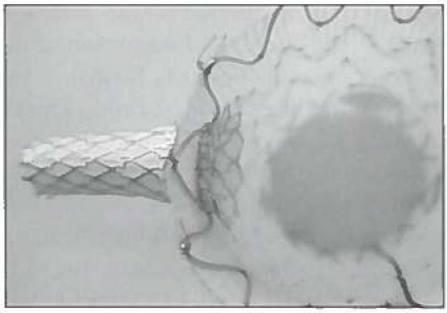


Figure 6. A covered stent inside a fenestration, turning a fenestrated graft into a branched graft.

- ***Abdominal branched***

  There are no human clinical papers yet focusing on this specific category only. This is partially due to an overlap with the previous technique. Indeed, the use of the same abdominal fenestrated technique with a covered stent instead of a bare stent changes the allocation of the procedure into this category (figure 6). Some articles in the previous category included patients with virtually no proximal neck, whose aneurysms were therefore treated with a covered stent inside the small fenestration. This is only successful if the connection between the covered stent and the main stent-graft is both hemostatic and secure. The use of reinforced fenestrations should improve hemostasis and secure fixation. The technique has also been used in suprarenal aneurysms where a gap had to be bridged. It is obvious that the longer the gap, the higher the risk of disconnection and endoleak. A fully branched technique may therefore be a better solution. Wisselink et al. presented in vitro and animal experimental work with abdominal branched grafts to accommodate the renal arteries.[24] They used fenestrated thin-walled expanded polytetrafluoroethylene (e-PTFE) tube grafts fitted with metal rings and inserted e-PTFE tube grafts mounted on Palmaz stents (Palmaz P308, Cordis Endovascular, Johnson

& Johnson Co., Warren, NJ, USA) fitted with identical metal rings at the end as side branches. Recently, they used a modification of their device, including a coupling system to secure the side branches (figure 7). Although conceptually very interesting, there has not been evolution into human clinical application up to now. Hosokawa et al. published two patients with suprarenal aortic aneurysms treated by a triple-branched graft developed by Inoue et al. to target both renal arteries and the superior mesenteric artery.[25] The concept seems to be difficult, although the basis is similar to the fenestrated technique: the main tube graft is kept constricted to allow catheterization of side branches and targeted vessels. To allow this catheterization, they use traction wires and loop catheters that pass the main device, but create a large loop and turn back into each individual side branch. After successful catheterization of the three targeted vessels, the side branches are simultaneously positioned inside the targeted vessels by pulling the whole device downwards. After good positioning, the main body can be fully deployed as well as the three side branches. Ballooning completes the first part of the procedure to be followed by the insertion of the bifurcated part.

- ***Thoraco-abdominal fenestrated***
  Stanley et al. published a case with a TAAA reaching to 0.5 cm above the celiac trunk.[20] They used the first version of the Cook Zenith thoracic stent-graft (William A. Cook Australia Pty. Ltd., Brisbane, Australia) with a fenestration in the distal part to accommodate the celiac trunk. This first version resembled the abdominal device in terms of design, and could therefore be catheterized from below after partial deployment (figure 8). At this moment, the thoracic device has been modified: it features a bare spring with reverse hooks distally and hooks without a bare spring proximally. Reason for this modification was to have a better fixation distally, thereby avoiding migration upwards due to the vector forces. With the current thoracic Cook Zenith TX1 and TX2 devices (William A. Cook Australia Pty. Ltd., Brisbane, Australia) it is also possible to create a fenestrated stent-graft with a distal large

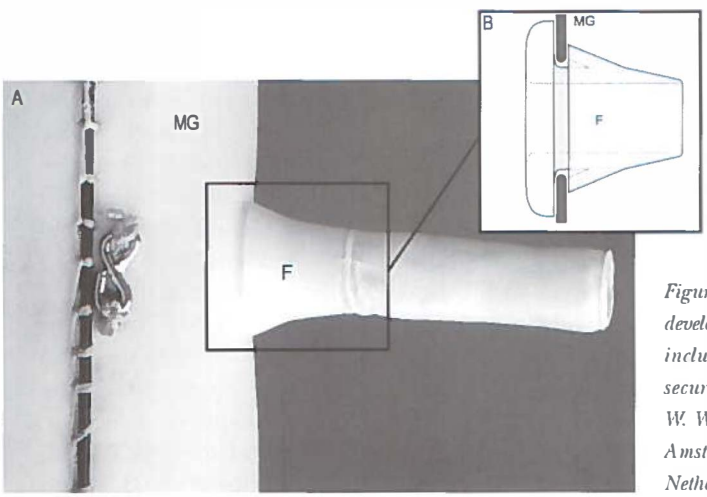


Figure 7. Branched graft model developed by Wisselink et al., including a coupling system to secure a side branch (courtesy of W. Wisselink, University of Amsterdam, Amsterdam, The Netherlands).

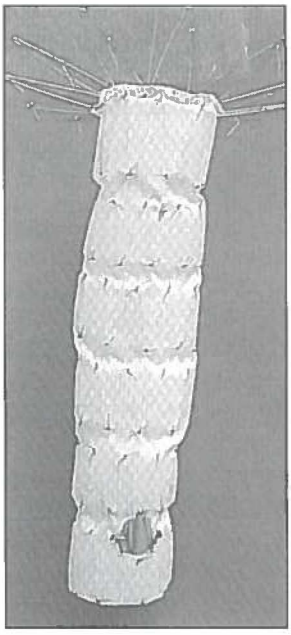


Figure 8. First generation Cook Zenith thoracic graft with distal fenestration.

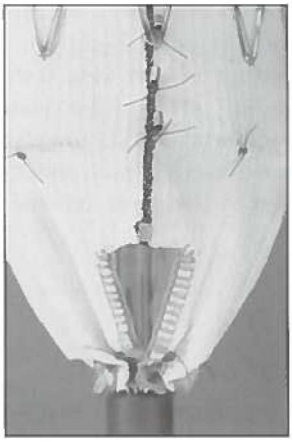


Figure 9. Current Cook Zenith thoracic graft with distal scallop.

scallop (figure 9). Although not published yet, it has been used in TAAA's with an overly short neck above the celiac trunk. Another treatment indication is the type I distal endoleak with an overly short neck, after previous thoracic stent-grafting, due to extension of disease distally. The technique involves a brachial approach and catheterization of the celiac trunk from inside the graft. To achieve this, the graft is, as in the abdominal fenestrated technique, opened only partially thanks to diameter reducing ties. In addition, one of the three attached top leafs can be opened by pulling a trigger wire, allowing access from above (figure 10a). A balloon is inserted over the catheterized scallop and celiac trunk, and inflated (figure 10b). In this way, the graft position is accurate, and full deployment can be achieved. A hybrid solution has been proposed by Lawrence-Brown et al.[26] They published two cases

Figure 10a. Opening of one of the three top leafs attached to the central catheter in order to allow entry of wire and catheterization of distal scallop and celiac trunk.

Figure 10b. Catheterization of celiac trunk through the scallop.

with a similar anatomy, i.e. a short distal neck with regard to the celiac trunk, but created a sufficient neck for endovascular therapy by circumscribing the aorta and distal end of the endograft with a 15 mm wide Dacron band. This was achieved through a midline laparotomy. In both cases the celiac trunk was divided and both ends were oversewn. This was undertaken after test clamping and pressure measurement in the splenic and hepatic arteries (both times 70-80 mm Hg). The Dacron band was subsequently sutured to the aorta and the distal part of the endograft (figure 11).

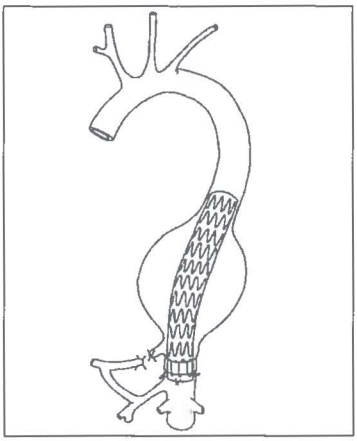


Figure 11. Hybrid open and endovascular technique to treat TAAA's reaching to the celiac trunk. (Courtesy of M. Lawrence-Brown and J. Semmens, Royal Perth Hospital, Perth, Australia).

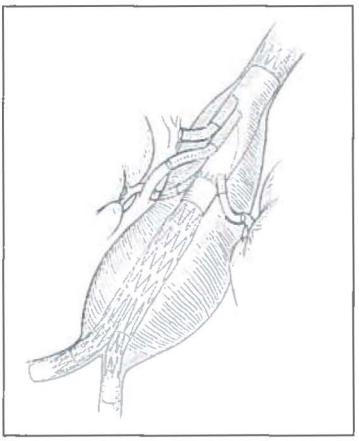
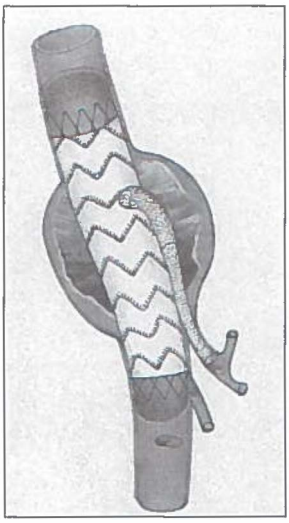


Figure 12a. Development of four-branched grafts by Chuter to treat TAAA's. (Courtesy of T. Chuter, University of California, San Francisco, U.S.A.).

Figure 12b: Example of a Cook Zenith four-branched graft.

Figure 13. A one-branched Medtronic Talent device with a Gore Hemobahn as used by Bleyn et al. (Courtesy of J. Bleyn, Antwerp Blood Vessel Center, Antwerp, Belgium).



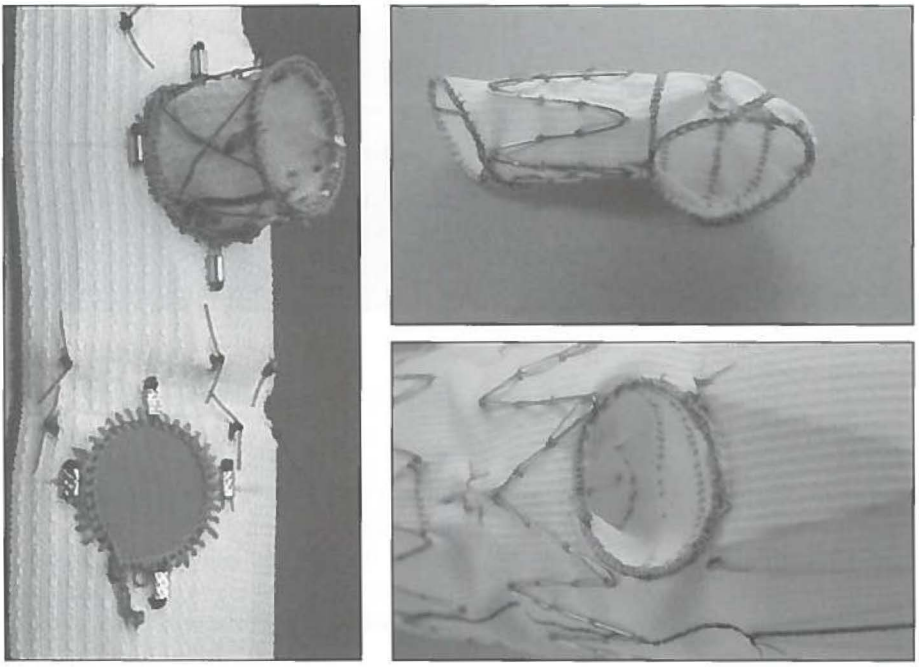


Figure 14a. A radially oriented branch.
Figure 14b. An internal side branch providing a long seal for the bridging stent-graft.
Figure 14c. Internal side branch in main graft.

- ***Thoraco-abdominal branched***
  Literature review Chuter deserves major credit for initiating the development in this area. He has been involved with stent-grafting from the early beginning, and was the first to attempt treatment of TAAA's by endovascular means with four-branched grafts.[27,28] (figure 12a) The technique involves catheterization of all side branches from the arm, to insert bridging stent-grafts in each side branch/targeted vessel (figure 12b). This brachial route is difficult, because it is long and tortuous. Catheterization and tractability/ pushability of the bridging stent-graft can prove extremely difficult. Nevertheless, patients have been treated in a few centers with success using these branched grafts. The first case report in this category was published already in 1997 by Inoue et al. using a one-branched graft to maintain flow into the celiac trunk.[29] Catheterization and positioning of the side branch was achieved through the contralateral femoral artery, before full deployment of the main body. Bleyn et al. published a similar case in 2002, but they catheterized the side branch after full deployment of the graft, and from above.[30] (figure 13) In contrast to Inoue et al., they used a bridging stent-graft to overcome the gap, where Inoue et al. were pushing the side branch into the targeted vessel directly. Some authors have chosen a combined endovascular and open surgical approach to these

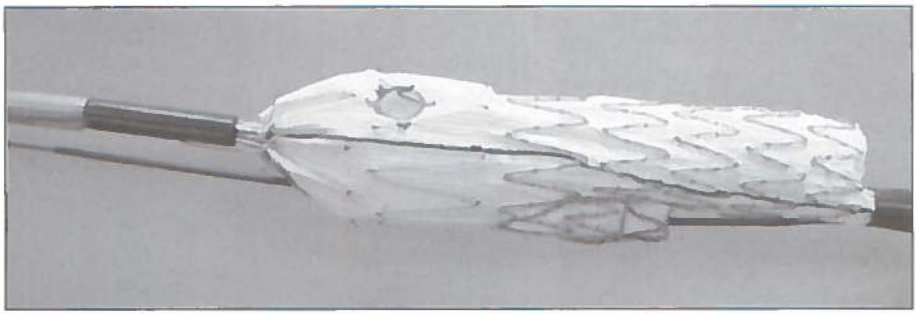


Figure 15. Indwelling wire positioned in the side branch.

aneurysms. The technique involves relocating of the visceral vessels, prior to the stent-grafting of the whole aorta.[31-33]

Evolution New types of branches are currently in development. They include short radially oriented cuffs and internal branches (figure 14a, figure 14b, figure 14c). These could provide an improved seal with the use of bridging stent-grafts. Indwelling wires may help the catheterization process as well as to retain position of sheaths coming from the arm (figure 15). The indwelling wire can be snared from above, thus creating a through-and-through wire. The sheath can be advanced and kept into position over this wire, and the bridging stent-graft can be advanced with more ease over another co-axial wire. This method helps creating tractability/ pushability during introduction of bridging stent-grafts. New flexor sheaths will also help to facilitate this process.

- ***Thoracic fenestrated and branched***
  These two categories can be discussed in one paragraph. The thoracic arch remains a very difficult area for stent-grafting at all, firstly due to its anatomy. At this level, the aorta is wide, tortuous, and mobile. In addition, there is a high flow rate. Another problem is the distance between insertion of the graft (i.e. the femoral artery) and the deployment zone (i.e. the arch), which makes handling and controlled deployment (orientation and positioning) difficult. This makes the idea of using fenestrations and branches in this area not very appealing, especially because the vital branches of the arch do supply the brain, with no tolerance for ischemia. In addition, there are good surgical alternatives, with different options to relocate of the supra-aortic branches, with the goal to create a proximal neck.[34-36]
  Inoue et al. were the first to report full arch reconstruction by endovascular means with a home-made triple branched graft. The stent-graft was a woven Dacron fabric graft supported by multiple rings of extra-flexible wire. Each branch had to be pulled inside the targeted vessel by snaring a traction wire attached to the branch. In a series of 15 patients, 14 one-branched and one three-branched grafts were deployed to exclude an aneurysm, with a primary success (i.e. complete exclusion of the aneurysm on CT scanning and/or arteriography before discharge) of 60%.[37,38] Among the failures were two patients in whom access with the 22 F sheath proved infeasible due to tortuous and small iliac arteries. Saito et al. published a

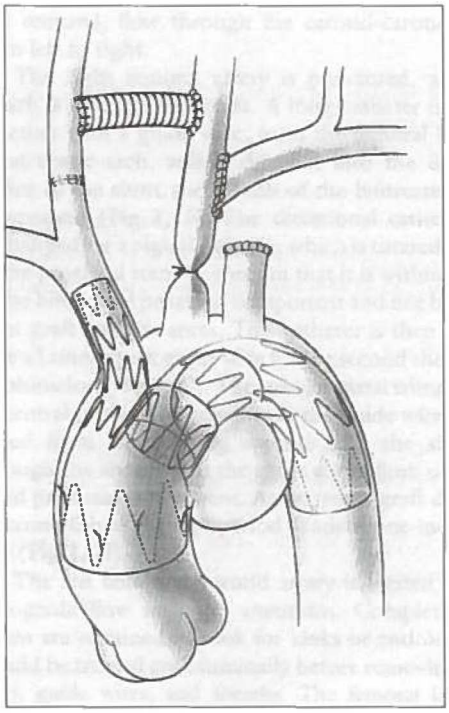


Figure 16. Branched graft technique to treat an arch aneurysm as used by Chuter. The main device is inserted through the right carotid, the bridging limb from the femoral artery. (Courtesy of T. Chuter, University of California, San Francisco, U.S.A.).

similar case, also using a single-branched home-made Inoue-graft to treat an aneurysm of the ductus diverticulum.[39] Finally, Chuter et al. published an interesting paper on development ideas with regard to branched arch grafts.[40] They also reported a successful case, in which they first relocated the left subclavian artery and the left carotid artery, and subsequently inserted a bifurcated graft from the right carotid into the ascending aorta. The second limb was catheterized from a femoral approach, and a limb stent-graft inserted to exclude the arch aneurysm.[41] (figure 16)

- ***Future considerations***

  The rapidly evolving application of stent-grafts for thoraco-abdominal aneurysms seems obvious and will further expand in the next decade. New developments for the near future include further use of reinforced fenestrations, indwelling catheters and flexor sheaths, as well as the use of new type branches, such as inner branches and reinforced radially orientated short branches. However, meticulous work-up is required, as well as precise hand-made manufacturing. It is also clear that insertion and deployment of these devices require a great deal of technical expertise. Therefore, most of the facilitated endovascular techniques previously described are not amenable to widespread application yet and should, to our opinion, be reserved to expert centers. Efforts to alter devices into simpler modular devices should be encouraged. Inevitably, long-term follow-up will determine the exact fate of these promising new techniques, before wider adoption can be recommended.

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Chapter IX

■ SUMMARY AND CONCLUSIONS

CHAPTER I

Chapter I describes the outline and rationale of this thesis.

CHAPTER II

- ***Background***
  Although the initial results of endovascular repair of abdominal aortic aneurysms were promising, current evidence from controlled studies does not convincingly show a reduction of 30-day mortality relative to that achieved with open repair.

- ***Methods***
  We conducted a multicenter, randomized trial comparing open repair with endovascular repair in 345 patients who had received a diagnosis of abdominal aortic aneurysm of at least 5 cm in diameter and who were considered suitable candidates for both techniques. The outcome events analyzed were operative (30-day) mortality and two composite endpoints of operative mortality and severe complications and operative mortality and moderate or severe complications.

- ***Results***
  The operative mortality rate was 4.6 percent in the open repair group (8 of 174 patients; 95 percent confidence interval, 2.0 to 8.9 percent) and 1.2 percent in the endovascular-repair group (2 of 171 patients; 95 percent confidence interval, 0.1 to 4.2 percent), resulting in a risk ratio of 3.9 (95 percent confidence interval 0.9 to 32.9). The combined rate of operative mortality and severe complications was 9.8 percent in the open-repair group (17 of 174 patients; 95 percent confidence interval 5.8 to 15.2 percent) and 4.7 percent in the endovascular-repair group (8 of 171 patients; 95 percent confidence interval, 2.0 to 9.0 percent), resulting in a risk ratio of 2.1 (95 percent confidence interval 0.9 – 5.4).

- ***Conclusions***
  On the basis of the overall results of this trial, endovascular repair is preferable to open repair in patients who have an abdominal aortic aneurysm of at least 5 cm in diameter. Long-term follow-up is needed to determine whether this advantage is sustained.

CHAPTER III

- ***Objectives***
  This study reports the results of a prospective continuous cohort of patients treated for endovascular aneurysm repair (EVAR) with a unified anesthetic strategy, based on the use of local anesthesia (LA) in all patients, while reserving regional (RA) or general anesthesia (GA) only to those with pre-defined individual- or surgical-specific indications.

- ***Methods***
  All patients treated by EVAR for an elective AAA between April 1998 and December 2003 were included. The strategy of treatment generated three cohorts of patients (LA, RA, or GA). Primary outcome included all cause mortality, non-fatal cardiac morbidity, respiratory complications, and renal failure. Secondary outcome measures included conversion to general anesthesia, use of analgesics, and time related outcomes (operating time, length of stay in intensive care unit and hospital, time required to resume oral intake, and time to ambulation).

- ***Results***
  A total of 239 patients underwent EVAR: 170 LA, 31 RA, and 38 GA. LA was associated with a lower incidence of complications compared to GA (P<.001). In the LA group, two patients had to be converted to GA, one because of a dissection, and one because of anxiety. In 13% of the patients in the LA group, additional IV sedation or IV analgesia was required. Operating time and length of stay in intensive care was shorter in the LA and RA group than in the GA group (P<.001). Length of stay in hospital, and time to ambulation and regular diet was shorter in the LA group compared with the RA and GA group (P<.001).

- ***Conclusions***
  A strategy, based on the preferential use of LA for EVAR restricting RA or GA only to those with pre-defined contra-indications is feasible and appears to be well tolerated.

■ CHAPTER IV

- ***Purpose***
  To describe frequency, type, and outcomes of re-interventions after endovascular aortic aneurysm repair (EVAR).

- ***Methods***
  Between September 1996 and December 2003, 308 patients were treated, with data collected prospectively. No patient was lost to follow-up, but two were excluded (one primary conversion, and one post-operative death). Vanguard, Talent, Excluder, Zenith, and Quantum devices were used. Follow-up required a CT scan before discharge. Initially, a CT scan was done at each follow-up. Subsequently, we used duplex ultrasound and abdominal X-ray, with CT scan used selectively.

- ***Results***
  Mean follow-up was 36±22 months. Re-interventions were required in 47 (15%) patients, 31 (66%) elective and 16 (34%) emergency cases. In 32 patients, the primary re-intervention was successful; in 15 patients an additional 13 secondary and four tertiary re-interventions were required. A total of 72 adjunctive manoeuvres were performed: 49 endovascular (68%) and 23 open (32%). The success of endovascular re-interventions was 80%. The success of open re-

interventions was 96%. Open conversions were required in nine patients (3%). There was no mortality.

- *Conclusion*
  EVAR was associated with a low burden of re-interventions, with only 15% patients requiring re-intervention. Our long-term follow-up, without regular CT, was simple and effective.

■ CHAPTER V

- *Purpose*
  To evaluate endovascular repair of abdominal aortic aneurysms (AAA) under local anesthesia in the acute setting.

- *Methods*
  Between 1998 and 2001, 47 patients with an acute AAA were evaluated for endovascular repair after informed consent, provided they were in a stable, albeit hypotensive condition. The patients underwent urgent computed tomography to assess suitability for endovascular repair; 16 were eligible for stent-graft repair: nine were frank ruptures and seven were symptomatic aneurysms. Complications and outcome of endovascular repair were evaluated; mortality was compared to a contemporaneous surgical cohort.

- *Results*
  Seven (23%) of 31 patients having a standard surgical procedure died in the study period compared to one (6%) of 16 patients undergoing endovascular repair (following conversion to surgery because of calcified access vessels). Twelve (75%) of the endovascular repairs were performed under local anesthesia; no complications with this mode of anesthesia were encountered. The median duration of the endovascular procedures was 110 minutes (range 75–240); median blood loss was 250 mL (range 100–2800 mL). Only four patients required blood transfusion, and only eight patients required admission to the intensive care unit. There were three post-operative complications (1 ischaemic colitis, 1 renal failure, 1 groin hematoma). During follow-up, three endograft patients received stent-graft extensions in uneventful procedures. Two patients died at 9 and 16 months from cardiac causes.

- *Conclusions*
  This study demonstrates the feasibility and possible advantages of endovascular repair under local anesthesia in selected acute AAA patients. Further studies are needed to prove the advantages over open repair.

CHAPTER VI

- ***Objectives***
  To analyze the results of emergency endovascular aneurysm repair (eEVAR) for acute abdominal aortic aneurysms (AAA), in comparison to open repair, and to evaluate suitability and application rate.

- ***Patients and Methods***
  All patients treated for an acute AAA between January 1998 and August 2004 were included. The primary outcome measure was in-hospital mortality. Secondary outcome measures were procedure time, intra-operative bloodloss, transfusion requirement, intensive care unit, and hospital length of stay. Suitability and application rate for eEVAR were assessed in a subgroup of patients, from January 2003.

- ***Results***
  A total of 253 patients were treated. eEVAR was performed in 40 patients, five (13%) died in-hospital. Open repair was performed in 213 patients, 64 (30%) died in-hospital. Secondary outcome measures were all significantly improved in the eEVAR subgroup.
  From January 2003 on, 56 patients were treated. Of the 44 (79%) patients who were evaluated for eEVAR, 16 (36%) patients were anatomically suitable. Eventually, 15 out of the 56 (27%) patients were treated by eVAR.

- ***Conclusion***
  The results of eEVAR in a selected group of patients are promising, but suitability and application rate were low.

CHAPTER VII

- ***Introduction***
  A proximal neck of 15 mm length is usually required to allow endovascular repair of abdominal aortic aneurysms (EVAR). Many patients have been refused EVAR due to a short neck. By customising fenestrated grafts to the patients' anatomy, we can offer an endovascular solution, especially for patients who are unfit for open repair.

- ***Methods***
  Eighteen patients were selected for fenestrated stent-grafting if they presented with an abdominal aneurysm of at least 55 mm in diameter, a short neck (less than 15 mm), plus contra-indications for open repair (cardiopulmonary impairment or a hostile abdomen). The stent-graft used was a customised fenestrated model based on the Cook Zenith® composite system. We used additional stents to ensure apposition of the fenestrations with the side branches.

- ***Results***
  All endovascular procedures were successful. Out of the 46 targeted side branches (10 superior mesenteric arteries, 36 renal arteries), 45 were patent at the end of the procedure. One accessory renal artery became occluded by the stent-graft. There was one possible proximal type I endoleak, which later proved to be a type II endoleak. There was no mortality, but complications occurred in six patients: two cardiac complications, three urinary complications and one occlusion of a renal artery. At follow-up (mean 9.4 months, range 1-18), there were no additional renal complications and all the remaining targeted vessels stayed patent.

- ***Discussion***
  By customizing fenestrated stent-grafts, it is possible to position the first covered stent completely inside the proximal neck, thus achieving a more stable position. The additional side-stents may also contribute to a better fixation. This technique may become a valuable alternative for patients who are at risk from open surgery.

■ CHAPTER VIII

Since 1991, endovascular aortic aneurysm repair (EVAR) has been established as an alternative for open surgical repair of aortic aneurysms. One of the main limitations for EVAR is the need for a sufficient sealing zone below or above vital aortic side branches. Recently, efforts have been made to overcome these limitations by incorporating fenestrations or branches in customized stent-grafts. This paper reviews the technical and clinical possibilities, as well as the results with fenestrated and branched stent-grafts. All these techniques can be classified into 6 groups, including abdominal fenestrated, abdominal branched, thoraco-abdominal fenestrated, thoraco-abdominal branched, thoracic fenestrated, and thoracic branched stent-grafting. The only well-elaborated technique at this moment is abdominal fenestrated stent-grafting. Currently, branched stent-grafting must be regarded as experimental, but advancements are taking place rapidly. It is anticipated that wider adoption will take place in the near future. New developments include the further use of reinforced fenestrations, indwelling catheters and flexor sheaths, as well as the use of new type branches.

Chapter X

■ SAMENVATTING EN CONCLUSIES

■ HOOFDSTUK I

In hoofdstuk I zijn de achtergronden van de opzet van dit proefschrift beschreven

■ HOOFDSTUK II

- ***Inleiding***
  Hoewel de eerste resultaten van de endovasculaire behandeling van aneurysmata van de aorta abdominalis (AAA) veelbelovend waren, tonen de uitkomsten van gecontroleerde onderzoeken niet overtuigend aan dat de operatiemortaliteit (dat is de mortaliteit binnen 30 dagen na de ingreep) lager is dan die na een open behandeling.

- ***Materiaal en methoden***
  Er werd een multicentrisch, gerandomiseerd onderzoek uitgevoerd om de open behandeling te vergelijken met de endovasculaire behandeling. In het onderzoek werden 345 patiënten opgenomen bij wie een AAA met een diameter van tenminste vijf cm was vastgesteld en die voor beide behandelingsmethoden in aanmerking konden komen. De operatiemortaliteit was een eindpunt van het onderzoek. Daarnaast waren er twee samengestelde eindpunten, namelijk de operatieve mortaliteit plus ernstige complicaties en de operatieve mortaliteit plus matig-ernstige of ernstige complicaties.

- ***Resultaten***
  De operatieve mortaliteit was 4,6% in de open behandelde groep (8 van de 174 patiënten; 95%-betrouwbaarheidsinterval 2,0 tot 8,9%) en 1,2% in de endovasculair behandelde groep (2 van de 171 patiënten: 95%-betrouwbaarheidsinterval 0,1 tot 4,2%). Dit betekent een risk ratio van 3,9 (95%-betrouwbaarheidsinterval 0,9 tot 32,9). De frequentie van operatieve mortaliteit plus ernstige complicaties was 9,8% in de open behandelde groep (17 van de 174 patiënten; 95%-betrouwbaarheids-interval 5,8 tot 15,2%) en 4,7% in de endovasculair behandelde groep (8 van de 171 patiënten; 95%-betrouwbaarheidsinterval 2,0 tot 9,0). Dit betekent een risk ratio van 2,1 (95%-betrouwbaarheidsinterval 0,9 tot 5,4).

- ***Conclusies***
  Uit dit onderzoek blijkt dat endovasculaire behandeling de voorkeur verdient boven open behandeling bij patiënten die een AAA hebben met een diameter van tenminste vijf cm. Langduriger follow-up is noodzakelijk om vast te stellen of dit voordeel ook op de lange termijn blijft bestaan.

■ HOOFDSTUK III

Doel

Dit onderzoek beschrijft een aaneengesloten cohort van endovasculair behandelde patiënten bij wie een uniforme anesthesie-strategie is toegepast. Hierbij werd lokale anesthesie (LA) als eerste keus gebruikt. Regionale (RA) of algehele anesthesie (GA) werden alleen toegepast in bepaalde patiënt- en techniek-specifieke situaties met helder gedefinieerde contra-indicaties tegen LA.

Materiaal en methoden

Alle patiënten die tussen april 1998 en december 2003 een electieve endovasculaire behandeling van een AAA ondergingen werden geïncludeerd. Door de anesthesie-strategie ontstonden drie groepen patiënten (LA, RA of GA). De primaire eind-punten waren mortaliteit, niet-fatale cardiale morbiditeit, respiratoire complicaties en nierinsufficiëntie. De secundaire eindpunten waren conversie naar algehele anesthesie, gebruik van analgetica, en verschillende tijdsvariabelen (duur van de ingreep, duur van het verblijf in de intensive care-afdeling en in het ziekenhuis, tijd tot de hervatting van de orale voeding, en tijd tot volledige mobilisatie).

- *Resultaten*

  In totaal ondergingen 239 patiënten een endovasculaire behandeling: 170 met LA, 31 met RA en 38 met GA. LA ging gepaard met een lagere incidentie van complicaties dan GA ($p<0,001$). In de LA-groep vond tweemaal conversie naar GA plaats, éénmaal wegens een dissectie en éénmaal wegens onrust van de patiënt. Bij 13% van de patiënten in de LA-groep was aanvullende intraveneuze sedatie of intraveneuze analgesie nodig. De duur van de ingreep was korter in de LA- en in de RA-groep dan in de GA-groep ($p<0,001$). De duur van het verblijf in het ziekenhuis, de tijd tot mobilisatie, en de tijd tot het hervatten van orale voeding waren korter in de LA-groep dan in de RA- en in de GA-groep ($p<0,001$).

- *Conclusies*

  Een anesthesie-strategie met LA als eerste keuze, waarbij RA of GA alleen wordt toegepast bij patiënten met goed gedefinieerde contra-indicaties tegen LA, is veilig en wordt door de patiënten goed verdragen.

■ HOOFDSTUK IV

- ***Doel***
  Dit onderzoek beschrijft de frequentie, het type en de uitkomst van re-interventies na endovasculaire behandeling van een AAA.

- ***Materiaal en methoden***
  Tussen september 1996 en december 2003 werden 308 patiënten behandeld. Alle patiënten werden gevolgd en hun gegevens werden prospectief verzameld. Twee patiënten werden uitgesloten (één onderging een primaire conversie, de ander overleed postoperatief). De volgende stent-grafts werden gebruikt: Vanguard, Talent, Excluder, Zenith en Quantum. Bij elke patiënt werd vóór ontslag een CT-scan gemaakt. Aanvankelijk werd ook bij elke poliklinische controle een CT-scan gemaakt. Later werd dit beperkt tot een een echografie en een buikoverzichtsfoto, met een CT-scan alleen op indicatie.

- ***Resultaten***
  De gemiddelde follow-up bedroeg 36±22 maanden. Bij 47 patiënten was een re-interventie noodzakelijk: 31 maal (66%) electief en 16 maal (34%) met spoed. Bij 32 patiënten was de eerste re-interventie geslaagd; bij 15 patiënten was een tweede, en bij vier een derde re-interventie noodzakelijk. Er werden in totaal 72 aanvullende verrichtingen uitgevoerd: 49 endovasculaire ingrepen (68%) en 23 open ingrepen (32%). Een endovasculaire re-interventie was geslaagd in 80% van de gevallen; een open re-interventie was geslaagd in 96% van de gevallen. Bij negen patiënten (3%) vond conversie naar een open procedure plaats. Geen enkele patiënt overleed na een re-interventie.

- ***Conclusies***
  Endovasculaire behandeling van een AAA bij daartoe geschikte patiënten maakt een open behandeling bij 97% van die patiënten overbodig en gaat gepaard met een gering percentage re-interventies. Follow-up met echografie en buikoverzicht-foto is eenvoudig en effectief.

■ HOOFDSTUK V

- *Doel*
  In dit onderzoek wordt bekeken of het mogelijk is acute AAA's endovasculair te behandelen onder locale anesthesie.

- *Materiaal en methoden*
  Van 1998 tot en met 2001 werden 47 patiënten met een acuut AAA beoordeeld op hun geschiktheid voor een endovasculaire behandeling. Van alle patiënten werd een "informed consent" verkregen. Met een spoed CT-scan werd vastgesteld of het AAA anatomisch geschikt was voor endovasculaire behandeling. Van de 47 patiënten kwamen er 16 in aanmerking voor implantatie van een stent-graft: negen hadden een bewezen ruptuur en zeven hadden een niet-geruptureerd acuut AAA. De complicaties van de endovasculaire behandeling werden geëvalueerd. Tevens werd de mortaliteit van de endovasculair behandelde patiënten vergeleken met de mortaliteit van een groep patiënten die open behandeld werden voor dezelfde aandoening in dezelfde periode.

- *Resultaten*
  Van de 31 patiënten die een open operatieve behandeling ondergingen gedurende de onderzoeksperiode overleden er zeven (23%). Van de 16 patiënten die een endovasculaire behandeling kregen overleed er één (6%), en wel na conversie naar een open procedure wegens verkalkte liesvaten. Twaalf (75%) van de endovasculaire procedures werden uitgevoerd onder lokale anesthesie. De gemiddelde duur van de endovasculaire procedures bedroeg 123 minuten (75-240 min) en het bloedverlies was gemiddeld 250 ml (100-2800 ml). Slechts vier patiënten hadden een bloedtransfusie nodig, en slechts acht patiënten moesten worden opgenomen op de intensive care-afdeling. Er waren drie postoperatieve complicaties (eenmaal ischemische colitis, eenmaal nierinsufficiëntie, eenmaal een hematoom in de lies). In de loop van de follow-up periode werd bij drie endovasculair behandelde patiënten zonder problemen een aanvullende stent-graft geplaatst. Twee patiënten overleden door een cardiale oorzaak na negen en 16 maanden.

- *Conclusies*
  Uit dit onderzoek blijkt dat endovasculaire behandeling van geselecteerde patiënten met een acuut AAA onder lokale anesthesie uitvoerbaar is en voordelen zou kunnen bieden. Aanvullend onderzoek is nodig om de voordelen ten opzichte van open behandeling aan te tonen.

■ HOOFDSTUK VI

- *Doel*
  In dit onderzoek worden de resultaten geanalyseerd van de endovasculaire behandeling van acute AAA's in vergelijking met de open behandeling. Tevens wordt nagegaan welk percentage van de patiënten met een acuut AAA geschikt is voor endovasculaire behandeling.

- *Materiaal en methoden*
  Alle patiënten die tussen januari 1998 en augustus 2004 werden behandeld wegens een acuut AAA werden opgenomen in het onderzoek. Het primaire eindpunt was de ziekenhuismortaliteit. Secundaire eindpunten waren de duur van de procedure, het intra-operatieve bloedverlies, de transfusiebehoefte, de duur van het verblijf op de intensive care-afdeling en de duur van de ziekenhuisopname. De anatomische geschiktheid voor endovasculaire behandeling werd vanaf januari 2003 beoordeeld in een subgroep van patiënten.

- *Resultaten*
  In totaal werden 253 patiënten behandeld. Bij 40 patiënten werd een endovasculaire procedure uitgevoerd, met een ziekenhuismortaliteit van vijf patiënten (13%). Een open behandeling werd uitgevoerd bij 213 patiënten, met een mortaliteit van 64 patiënten (30%). Alle tijdsvariabelen (secundaire eindpunten) waren significant beter in de endovasculaire groep. Vanaf januari 2003 werden 56 patiënten behandeld wegens een acuut AAA. Twaalf van hen (21%) werden niet geëvalueerd naar geschiktheid voor endovasculaire behandeling. Van de 44 patiënten (79%) die wel werden geëvalueerd waren er 28 (64%) ongeschikt. Zestien patiënten (36%) waren anatomisch geschikt. Uiteindelijk werden 15 van de 56 patiënten (27%) endovasculair behandeld.

- *Conclusies*
  De resultaten van de endovasculaire behandeling van acute AAA's in een geselecteerde groep patiënten zijn veelbelovend, maar de anatomische geschiktheid voor endovasculaire behandeling en derhalve de toepasbaarheid daarvan is laag in deze categorie van patiënten.

■ HOOFDSTUK VII

- ***Inleiding***
  De endovasculaire techniek voor de behandeling van een AAA vereist meestal een proximale hals van het aneurysma met een lengte van tenminste 15 mm. Veel patiënten worden afgewezen voor endovasculaire behandeling omdat de hals onder de nierarteriën te kort is. Door het vervaardigen van "gefenestreerde" stent-grafts, aangepast aan de individuele anatomie, kan dergelijke patiënten toch een endovasculaire oplossing worden geboden. Deze optie lijkt vooral aantrekkelijk voor patiënten met een hoog operatierisico.
- ***Materiaal en methoden***
  Achttien patiënten werden geselecteerd voor implantatie van een "gefenestreerde" stent-graft. Alle patiënten hadden een AAA van tenminste 55 mm in doorsnede, waarbij de proximale hals te kort was (minder dan 15 mm) voor de standaard endovasculaire behandeling. Bovendien moesten er contra-indicaties bestaan tegen een open behandeling, bijvoorbeeld cardiopulmonale contra-indicaties of contra-indicaties tengevolge van voorafgaande operaties in de buik. Alle patiënten werden behandeld met een "gefenestreerde" Cook Zenith® stent-graft. Alle operaties werden werden verricht in een operatiekamer. Follow-up werd verricht middels CT-scan, buikoverzichtsfoto en controle van de nierfunctie.

- ***Resultaten***
  Alle endovasculaire procedures waren geslaagd. Van de 46 geviseerde zijtakken (10 maal de arteria mesenterica superior en 36 maal een arteria renalis) waren er 45 aan het eind van de procedure doorgankelijk. Eén accessoire arteria renalis werd afgesloten door de stent-graft. Er bestond het vermoeden op één proximaal type I-endoleak, maar dat bleek later een type II-endoleak te zijn. Er was geen mortaliteit maar er deden zich bij zes patiënten complicaties voor: twee cardiale complicaties, drie urinewegcomplicaties, en een afsluiting van een arteria renalis. Tijdens de follow-up periode (gemiddeld 9,4 maanden) deden zich geen nieuwe complicaties voor.

- ***Conclusie***
  Door aanpassing van "gefenestreerde" stent-grafts kan de eerste afdichtende stent geheel binnen de proximale hals worden geplaatst, waardoor een stabielere positie wordt verkregen. Deze techniek biedt een waardevol alternatief bij patiënten die hoog risico-kandidaten zijn voor een open procedure. De twee belangrijkste risico's zijn het optreden van een proximaal type I-endoleak en occlusie van de geviseerde zijtakken. Gaandeweg hebben we routinegewijs stents geplaatst door de "fenestraties" heen om ervoor te zorgen dat de "fenestratie" precies tegenover de zijtak komt te liggen. Deze extra stents dragen mogelijk ook bij tot een betere fixatie van de stent-graft.

HOOFDSTUK VIII

Sinds 1991 vormt de endovasculaire behandeling van een AAA een alternatief voor de open chirurgische behandeling. Eén van de belangrijkste beperkingen van de endovasculaire behandeling is de noodzaak om boven en onder vitale zijtakken van de abdominale aorta voldoende ruimte te hebben voor het fixeren van de stent-graft. Sinds kort wordt getracht deze beperkingen op te heffen door het gebruik van stent-grafts waarin "fenestraties" of zijtakken zijn aangebracht. In dit artikel worden de technische en klinische mogelijkheden beschreven, alsmede de resultaten van het gebruik van "gefenestreerde" stent-grafts en stent-grafts met zijtakken. De verschillende technieken kunnen worden ingedeeld naar anatomische locatie: abdominaal "gefenestreerd", abdominaal met zijtakken, thoraco-abdominaal "gefenestreerd", thoraco-abdominaal met zijtakken, thoracaal "gefenestreerd" en thoracaal met zijtakken. Op dit moment is de enige techniek die zijn waarde heeft bewezen het gebruik van de abdominaal "gefenestreerde" graft. Behandeling met stent-grafts met zijtakken moet worden beschouwd als experimenteel, maar er worden op dit gebied snel vorderingen gemaakt. De verwachting is gerechtvaardigd dat deze technieken in de nabije toekomst op grotere schaal zullen worden toegepast. Nieuwe ontwikkelingen zijn de toepassing van verstevigde "fenestraties", speciale geprepositioneerde catheters en flexibele sheaths, evenals nieuwe types zijtakken.

Appendix i

THE MEMBERS OF THE DUTCH RANDOMISED ENDOVASCULAR ANEURYSM MANAGEMENT TRIAL GROUP WERE AS FOLLOWS:

Steering Committee
DE Grobbee, JD Blankensteijn, J. Buth, PM Pattynama, ELG Verhoeven, AE van Voorthuisen, and AAA Bak.

Executive committee
JD Blankensteijn, M Prinssen, MRHM van Sambeek, ELG Verhoeven, J Buth, PhWM Cuypers, R Balm, E Buskens, and DE. Grobbee.

Data monitoring and ethics committee:
MG Hunink , JM van Engelshoven
MJHM Jacobs, and BAJM de Mol.

Site & Device Selection Committee:
JH van Bockel, R. Balm, J Reekers, X. Tielbeek, ELG Verhoeven, and W Wisselink.

Data management and datamonitoring
N Boekema, and I Sikking

Outcome Adjudication Committee:
M Prinssen, R Balm, J Buth, MRHM van Sambeek, ELG Verhoeven, and JD Blankensteijn.

Data analysis:
JD Blankensteijn, M Prinssen, and E Buskens.

Clinical centers (number of patients randomised):
THE NETHERLANDS: Catharina Hospital Eindhoven – J Buth, AV Tielbeek (N=94); University Medical Center Utrecht – JD Blankensteijn (N=35); Academic Medical Center Amsterdam – R Balm, JA Reekers (N=32); Erasmus Medical Center Rotterdam – MRHM van Sambeek, P Pattynama (N=30); University Hospital Groningen – ELG Verhoeven, T. Prins (N=27); St. Franciscus Gasthuis Rotterdam – AC van der Ham, JJIM van der Velden (N=27); Rijnstate Hospital Arnhem – SMM van Sterkenburg, GB ten Haken (N=14); Leyenburg Hospital 's Gravenhage – CMA Bruijninckx, H van Overhagen (N=9); Albert Schweitzer Hospital Dordrecht – RP Tutein Nolthenius, TR Hendriksz (N=8); Atrium Medical Center Heerlen – JAW Teijink, HF Odink (N=8); MC Rijnmond Zuid Rotterdam – AAEA de Smet, D Vroegindeweij (N=7); Jeroen Bosch Hospital den Bosch – RMM van Loenhout, MJ Rutten (N=7); St. Elisabeth Hospital Tilburg – JF Hamming, LEH Lampmann (N=5); Maxima Medical Center Veldhoven – MHM Bender, H Pasmans (N=5); OLVG, Amsterdam – AC Vahl, C de Vries (N=5); Meander Medical Center Amersfoort – AJC Mackaay (N=4); Vlietland Hospital Schiedam – LMC van Dortmont (N=4); University Medical Center Nijmegen – D van der Vliet; L Schultze

Kool (N=4); Martini Hospital Groningen – JHB Boomsma, HR van Dop (N=3); MC Haaglanden 's Gravenhage – JCA de Mol van Otterloo, TPW de Rooij (N=3); Hospital Bernhoven Oss – TM Smits (N=3); Oosterschelde Hospital Goes – EN Yilmaz (N=3). VU Medical Center Amsterdam – W Wisselink, FG van den Berg (N=2); Leiden University Medical Center – MJT Visser, E van der Linden (N=1); University Medical Center Maastricht – GWH Schurink, M. de Haan (N=1); Bronovo Hospital 's Gravenhage – HJ Smeets (N=1)
BELGIUM: St Jozef Hospital Turnhout – P Stabel (N=4); St. Trudo Hospital St. Truiden – F van Elst (N=3); University Hospital Antwerpen – J Poniewierski (N=1); University Medical Center Gent – FEG Vermassen (N=1).

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Curriculum vitae

Eric Verhoeven was born on September 27, 1960, in Arlon, Belgium.

In 1978, he graduated from high school in Bensberg (Germany), and started to study Medicine, at the Universities of Diepenbeek and Leuven (Belgium), where he graduated in 1988.

For the next 2.5 years, he worked as a resident in general surgery in Leuven (head: Prof.dr J.A. Gruwez). Thereafter, he worked as a resident for six months in Deinze (Belgium, Dr L. Berwouts and Dr J. Lagast), one year in Bonheiden (Belgium, Dr P. Peeters), and one year in Exeter (United Kingdom, Prof.dr W.B. Campbell). In 1993, he became chief-resident in Leuven (head: Prof.dr P.L.O. Broos), and completed his surgical education in 1994.

Thereafter, he moved to The Netherlands for a fellowship in Vascular Surgery at the Department of Surgery of the University Medical Center Groningen (head: Prof.dr R. van Schilfgaarde). He was appointed as consultant vascular surgeon in the same hospital one year later.

Together with his colleagues, he developed the endovascular program, which led to this thesis.